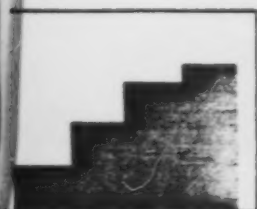


B5450-7-F



MARKETDATA ENTERPRISES

Full Service Market Research & Consulting

P.O. Box 436
Lynbrook, N.Y. 11563

Phone: 516-599-8128

THE MEDICAL LABORATORIES INDUSTRY - OPPORTUNITY AMIDST TURMOIL

(A Strategic Marketing, Technological, And Economic
Status Report, Analysis, and Future Outlook)

This business information report has been prepared by using a comprehensive variety of "secondary" sources, including Government health care agencies, clinical trade associations and journals, computer databases, directories, company annual reports, financial services, official Census Bureau statistics, surveys and articles, as well as "primary" research via nationwide telephone surveys conducted by Marketdata during March/April 1988.

The report is believed to be the most comprehensive and authoritative analysis of the clinical test laboratory industry available today. It will be equally applicable to: the owner or director of an independent commercial lab, director of an in-hospital lab, market research analyst of a major lab chain company, consultant, industry analyst, stock brokerage firm, or merger/acquisition candidate.

Publication Date: April 1988

© Copyright April, 1988, Marketdata Enterprises. Reproduction in whole or in part, by any means, without prior written consent of the copyright owner is strictly prohibited. Violators will be subject to full prosecution under U.S. copyright laws.

CONDITIONS OF PURCHASE

Much of the data used in this report is considered "public domain" (Commerce Dept. & Census Bureau government statistics, surveys and articles from **other** research firms, trade journals, trade associations, computer database abstracts, etc.). However, due to the **way** it has been re-worked and analyzed (Marketdata forecasts, rankings, re-calculations, etc.), plus proprietary information from phone surveys and other "primary" research, each study is intended solely for use only by the officers and employees of the company purchasing it.

The report is copyrighted, and its contents are not to be made available in any way to other persons or subsidiaries of the same company or other companies. Reproduction of any material is strictly forbidden without written permission of the publisher, and violators will be aggressively prosecuted by legal counsel.

ADDITIONAL COPIES

Additional copies of this report intended for use by the operating division for which the first copy is purchased may be obtained from Marketdata at a fraction of the cost of the original (usually 20% of the first copy price).

SUPPLEMENTARY MARKETDATA SERVICES

Purchasers of Marketdata reports are encouraged to inquire about additional research services. Marketdata provides custom research studies and management consulting, tailored to our client's needs in areas related to the enclosed report, but perhaps not covered in detail. Free project proposals (with time & cost estimates) are submitted upon learning your specific information needs. A consulting capabilities pamphlet is enclosed for your review and reference, describing the services offered.

THE MEDICAL LABORATORIES INDUSTRY - OPPORTUNITY AMIDST TURMOIL (April 1988)

TABLE OF CONTENTS

PAGE

INTRODUCTION: REPORT SCOPE & METHODOLOGY	1
---	----------

INDUSTRY OVERVIEW & EXECUTIVE RECOMMENDATIONS

* Overview of major industry problems, challenges, opportunities, market forecasts, structure of the industry, recommended strategies for growth/survival of independent labs vis-a-vis competition from physician in-office testing	5-14
--	------

INDUSTRY PROBLEMS, CRITICISMS, & THE FEDERAL REGULATORY CLIMATE

* Pap smear tests - discussion of error rates, market size, causes of errors, lab practices, etc.	15
* The federal response to the problem-summary of investigations, company & state cases	17
* Cholesterol tests - discussion of error rates, etc., as above	21

CORPORATE AND FEDERAL DRUG ABUSE TESTING

* Discussion of existing company programs, size & nature of the market, drug testing of federal workers (by 6 agencies)	24
* Urine drug tests-discussion of accuracy and reliability, proficiency testing of labs	27
* Alternative tests (hair, saliva analysis, blood drug tests)	29

AIDS TESTING

* Status report of new developments in testing (urine tests), scope of the problem, accuracy of tests-abstracts from 1987 Office of Technology Assessment hearings, problem of false positives, insurance company AIDS policies, etc.	32-36
---	-------

THE MEDICARE PAYMENT SYSTEM AND THE IMPACT OF DIAGNOSTIC RELATED GROUPS (DRGS)

* Discussion of DRGs' impact on: test activity, preadmission testing, capital spending, turnaround time, quality control, staffing by in-hospital labs	37
* Strategies used to control utilization, to regulate test ordering, and to ease financial pressures, tests dropping in volume	41

- * Discussion of HCFA prospective competitive bidding model, Medicare-estimated supplementary medical insurance disbursements to independent labs: 1975-86 46

CRITICAL LABOR/STAFF ISSUES FOR CLINICAL LABS

- * Results of 1987 Medical Lab Observer survey
 - * Salary trends-increases, starting salaries, forecasts 47
 - * Staff turnover, productivity, morale 48
 - * Employee benefits offered by labs 48, 53
 - * Affects of budget cutbacks 49
 - * 1987 starting salaries, by type & size lab, by region (for 6 lab functions from technician to lab director) 51, 52
 - * Supervisor salary comparisons, 1987, by type/size lab 51

SIZE AND STRUCTURE OF THE INDUSTRY, FUTURE PROSPECTS & FORECASTS

SIZE OF THE MARKET

- * Summary and discussion: Total market, blood cholesterol, Pap smear, drug testing, AIDS market segment sizes 54-59
- * Medical labs' annual receipts, as reported by Census Bureau's Service Annual Survey: 1978-86 actual, 1987-88 estimates, 1993 forecasts 60

STRUCTURE OF THE INDUSTRY

- (Independent labs, Hospital labs, Physician in-office testing)
- * Summary and discussion 61
- * Number of medical labs, by state: 1987 64
- * Number of clinical labs, by specialty performed: 1986 65
- * Medical & dental labs, by legal form of organization: 1982 (corporation, indiv. proprietorship, partnership, etc.) 66
- * Labs by single vs. multi-unit operations: 1982 67
- * Medical & dental labs, by receipts size of **lab** (under \$10,000-\$5 million +): 1982, receipts, annual payroll 68
- * Medical & dental labs, by annual receipts size of **firms**: 1982, no. of firms, labs, receipts, payroll, no. of employees 69
- * Medical & dental labs by employment size of firms (less than 5 employees-1000+): 1982 70
- * Medical & dental labs, by avg. receipts and no. of employees per lab: 1982 71

* Composite financial statement for medical labs as a group-average balance sheet/income statement/ratios: 1983-87	72
* Physician in-office labs - a status report	73
* Discussion of structure of the hospital lab market	75

RESULTS OF 1988 SURVEY OF LAB DIRECTORS

* Summarized findings of telephone survey of independent lab directors nationwide-major concerns, 1988 outlook and beyond, major concerns, usage/satisfaction with lab instrumentation, staffing, training, competitive/survival strategies, etc.	76-81
---	-------

SUMMARY OF RECENT MAJOR MARKET DEVELOPMENTS

* 38 Computer-searched database abstracts: bibliographic, full-text articles covering: industry consolidation, market size/forecasts, market trends, health & fitness tests, joint ventures, etc. (companies covered: American Medical Intl., Intl. Clinical Labs, Hoffman-LaRoche, Westmark Intl., Damon Clinical Labs, Biotherapeutics, Biodecision Labs, Nichols Institute, SmithKline Bio-Science, Johnson & Johnson, Pharmchem Labs, Scripps Clinic)	82-94
---	-------

PROFILES OF KEY INDUSTRY COMPETITORS

For most companies below: 1980-87 financial performance, divisional/business segment breakdowns, recent mergers or joint ventures, new marketing agreements, etc.

* Corning - MetPath	95
* Damon Clinical Laboratories	95-97
* International Clinical Laboratories/SmithKline Beckman	98-99
* National Health Laboratories	100
* Roche Biomedical Laboratories	101-02

THE CLINICAL LAB INSTRUMENTATION MARKET

* Overview of market trends and directions, profiles of major suppliers, discussion of electrophoresis, HPLC, spectroscopy, liquid scintillation, chromatography, microbiology, non-isotopic immunoassay, hematology-mkt. size/technologies/competitors	103
* Chemistry lab instruments, unit & dollar sales: 1980-86	110
* Hematology lab instruments, unit & dollar sales: 1980-86	110
* Microbiology lab instruments, unit & dollar sales: 1980-86	110
* Histology lab instruments, unit & dollar sales: 1980-86	110
* PH meters & electrodes, ion selective electrodes, electrophoresis chambers, coulometric analyzers: dollar sales-1976-1986	111

* Chromatographic instruments (gas, liquid, TLC, other), sample and flow counting systems: unit & dollar sales: 1976-86	112
* Photometers & other clinical lab instruments, unit & dollar sales: 1980-86	113
* Profiles of major instrument mfrs.--Abbott Labs, Becton Dickinson, Bio-Rad Labs, Kevex Corp., Nicolet Instrument Corp., Perkin-Elmer, Varian Associates	114-19
* Name & address listing of 166 major laboratory/medical/analytical equipment mfrs.	120-25

DIRECTORY OF MAJOR INDUSTRY TRADE ASSOCIATIONS, TRADE JOURNALS, AND NEWSLETTERS	126-27
--	--------

INTRODUCTION - STUDY SCOPE & INFORMATION SOURCES USED

A major source of public information about **any** industry or market analyzed by Marketdata is the U.S. Government--the most prolific producer of business information in the world. The **Standard Industrial Classification (SIC) System** was created to allow for the uniform collection and analysis of economic, marketing and financial statistics about **all** sectors of the U.S. economy. A 4-digit numerical code is assigned to each industry, with more detailed product line breakdowns available at the 5, 6 and 7-digit levels.

A major Census of businesses is performed every five years (years ending in a 2 or 7), producing a wealth of information. However, it generally takes two years after the survey is performed for the information to be printed and released. The user must accept this trade-off between the **quality** of the data and its **timeliness**.

The SIC system works so well that the private sector has embraced it as well. Mail list houses use it, as well as credit bureaus and financial directory publishers such as Standard & Poors, Dun & Bradstreet, TRW, Robert Morris Associates, etc.

For **this** report, the major code that was used was SIC code 8071, described in the 1987 Standard Industrial Classification Manual (Office of Management & Budget) as follows.....

8071.....Medical Laboratories

"Establishments primarily engaged in providing professional analytic or diagnostic services to the medical profession, or to the patient on prescription of a physician." These establishments include.....

- Bacteriological labs (not mfg.)
- Biological labs (not mfg.)
- Blood analysis labs
- Laboratories of biological chemists (not mfg.)
- Clinical medical laboratories
- Pathological laboratories
- Medical testing labs, analytic or diagnostic
- Urinalysis labs
- X-ray labs, including dental

SIC code **8071** represents information pertinent **only** to *medical* labs. These industry statistics are very useful, because such labs have many similarities, similar operating costs, and deal with the same kinds of customers. *Dental* labs are considered to be a totally separate industry, with its own SIC code--**8072**.

In addition, sales figures for the clinical lab instrumentation market were obtained by searching government reports for SIC **3832--Analytic and Scientific Instruments**.

The last Censuses (of Service Industries, Manufactures, Retail Trade) were performed in 1982, and are the latest available. The 1987 Census is now in progress, and information generated by it should become available by 1989. However, a more up-to-date report is issued each year (latest is for 1986). It is called the Service Annual Survey, and covers receipts of medical labs. In this report, we have compared 1982 Census data to 1977 figures, for trend analyses, wherever possible.

Marketdata believes that it is dangerous to rely on just **one** source, and therefore uses a *comprehensive* variety of information sources in **all** reports. Following are the sources used for this report.....

Government Reports/Publications

- * Service Annual Surveys-Current Business Reports: 1978-86
(U.S. Dept. of Commerce)
- * Census of Service Industries, Dept. of Commerce (1982, 1977)
- * Current Industrial Report MA 38B (Selected Instruments & Related Products): 1980-86
- * 1987 U.S. Statistical Abstract

Government Agencies & Their Special Surveys/Reports

- * Centers For Disease Control (CDC)
- * Government Accounting Office (GAO)
- * Health Care Financing Administration
- * National Center For Health Services Research
- * National Center For Health Statistics
- * National Institute of Health (NIH)
- * Office of Technology Assessment

Trade Associations & Their Staffs

- * American Association of Blood Banks
- * American Blood Resources Association
- * American Clinical Laboratory Association
- * American Red Cross
- * College of American Pathologists
- * Clinical Laboratory Management Association
- * Federal Drug Administration
- * Health Care Equipment Manufacturers' Association
- * Health Industry Manufacturers Association
- * National Association of Laboratory Suppliers

Trade Journals & Editorial Staffs

- * Medical Lab Observer

Financial Directories, Reports, Surveys

- * Dun & Bradstreet Million Dollar Directory - 1987
- * Standard & Poors Stock Sheets, Health Care Industry Survey
- * Value Line Investment Surveys
- * Robert Morris Associates-Annual Financial Statements

Newspapers & Periodicals

- * Business Week
- * The Wall Street Journal

Computerized Business Databases

- * Custom search of Predicasts "PROMT" (Predicast Overview of Markets & Technology) database

Company Annual Reports & Product Literature

Other Sources

- * American Business Lists-National Yellow Pages Directories

Original Marketdata Research

- * "Primary" phone interviews of independent commercial and hospital lab directors and supervisors nationwide

- * Discussions with trade association and trade journal staff personnel and editors, industry analysts, stock brokerage houses, affiliated research companies.

Several hundred phone calls were made by Marketdata, during March-April 1988, to lab directors and management nationwide. These discussions were extremely fruitful and insightful. Findings of this phone survey are summarized within the individual sections of the report, and led Marketdata to the recommended strategies provided. We'd like to thank the medical lab industry's leaders for sharing their time with us, and discussing their challenges, problems, and opportunities.

INDUSTRY OVERVIEW AND EXECUTIVE RECOMMENDATIONS

THE CREDIBILITY PROBLEM

Three congressional committees, two in the Senate and one in the House, recently began investigations of the country's \$20 billion clinical laboratory industry. The investigations began, in large part, as a response to a series of Wall Street Journal articles and Washington, DC area telecasts which disclosed that many widely-used lab tests such as Pap smears, AIDS tests, drug abuse screenings, and blood cholesterol tests are in error 20-40% of the time. Independent commercial labs have been accused of shoddy work and poor quality control procedures, the result of overworked, inadequately trained, and underpaid lab technicians, as well as dubious work practices, fraud allegations, and poor or nonexistent licensing and regulation of an industry growing too fast for its own good.

A critical cancer detection test, the Pap smear, is under close scrutiny, since erroneous results can mean life or death situations for patients. Many high-volume labs, dubbed "Pap mills" encourage technicians to take work home for analysis, or to handle volumes of tests far beyond recommended guidelines. In addition, the fast-growing physician in-office labs (POLs) market goes largely unregulated, by anyone.

Following are some of the major charges against the industry and its practitioners.....

- * 20-40% of Pap tests performed fail to detect cervical cancer.
- * For Pap analyses, lab technicians at federally certified labs are not required to pass proficiency tests: it is the only common lab procedure for which such a test is not required.
- * The Clinical Laboratories Improvement Act of the 1960s is a weakly-enforced law, and covers only a fraction of the nation's labs.
- * Lab quality control procedures are frequently inadequate.
- * Lab technicians are overworked, poorly trained, and are characterized by a high turnover rate due to dissatisfaction with hours and salary--many are leaving the profession entirely. Morale is poor. Proficiency testing of lab technicians is the exception rather than the rule.

- * Budget cuts, driven by the DRG system implemented four years ago (Diagnostic Related Groups), have forced many labs (especially in-hospital labs) to cut corners, and fosters severe price competition between independent labs for common tests. Piecework is encouraged, and leads to poor lab technician work habits that ultimately result in an increased error rate.
- * Erroneous test results occur frequently because of inadequate calibration of lab instrumentation and improper use of reagents. This is a key issue for the multitudes of private doctors using "black boxes" or analyzers being marketed by manufacturers. Statistics reveal that 60% of all lab tests are conducted in physicians' offices. Another study found that nearly 40% of people performing lab work in private doctors' offices may have no lab training at all.
- * Lab instruments may not be used correctly by technicians, or they may use chemical reagent/supplies not meant for their model of analyzer. In addition, lab reports' "normal" ranges can be interpreted very loosely by doctors, and are confusing-equipment producers often don't base the range on established links between cholesterol levels, for example, and coronary-artery disease. No standardized "protocol" (to ensure that different machines produce the same results) exists for manufacturers of lab instrumentation.
- * Doctors are accused of choosing labs for all types of medical tests based on availability of kickbacks rather than quality of services. Many labs offer these kickbacks in order to survive in a much more competitive market than years ago.
- * Labs are accused of charging two sets of prices, one for governmental beneficiaries and another for other customers.
- * The industry, due to demand for AIDS tests and federal and corporate drug abuse screening, is growing too fast to properly regulate itself.

SIZE OF THE INDUSTRY - MARKET SEGMENTS

The total clinical lab market in the United States is estimated to be worth \$19.8 billion in 1988. **Marketdata's forecast is for 13.5% average annual growth over the next five years, to a level reaching \$33.2 billion by 1993.**

We estimate that the test market is divided into three major test "segments", or different types of labs performing tests--1) in-hospital laboratories (which capture 46% of the test market), 2) independent commercial medical labs (which capture 28% of the market), and 3) physician-office labs or "POLs" (which account for an estimated 26% of the market).

Independent labs posted *actual* revenues of \$4.37 billion during 1986 (U.S. Census Bureau data--annual surveys). Marketdata estimates 12.5% annual growth in 1987 and 1988, to \$5.54 billion in the current year, and 13.2% yearly growth to \$9.9 billion by 1993.

In the short term, it is likely that independent labs and physician-office labs will capture a larger share of the overall test market. POLs are the fastest-growing, albeit totally unregulated industry market segment. **Independent labs are** affected by federally-mandated cuts in Medicare reimbursement fees (to about 50% of the costs, and projected to trend even lower), but not quite as severely as **in-hospital** labs. The latter have been hit hard by the DRG system, budget cuts, and newly-forced streamlining and efficiency measures.

Three fast-growth test areas of the future will be: 1) AIDS/infectious diseases of all kinds, 2) blood cholesterol, and 3) drug abuse screening. The American Red Cross, State Health Departments, and the American Association of Blood Banks will be strained to the limit in the next ten years, to handle the exponential increase in blood supply screening for AIDS. It is inevitable that most of the increased test activity will filter to the independent commercial labs able to obtain the necessary state and city licenses for AIDS testing. In addition, the general public's heightened awareness of cardiac health will spur more blood cholesterol tests, and corporate America's emerging crackdown on drug abuse should fuel this market as well.

AIDS testing is estimated to represent a potential \$95-105 million year market now, and will grow the fastest of all test procedures. Currently, 70% of all AIDS tests are performed by **public health agencies** such as the 2,400+ institutional members of the American Association of Blood Banks, Community Council of Blood Centers, the Red Cross, 600 hospital blood banks, and 1,500+ hospital transfusion services. The 14 million units of blood donated each year are all screened for AIDS, syphilis, hepatitis, etc. This blood bank market, at \$2 per test, represents a \$28 million yearly market.

The second largest AIDS testing market would have to be the military, which screens several million enlisted personnel each year. This is probably a market segment in the \$10 million range.

Third is the **individual patient, non-military, non-blood bank** test market, estimated by national blood bank associations to total 800,000 tests during 1988, up from 550,000 in 1987. Prices and volumes of these tests, and therefore total market potential, are difficult to pin down exactly. The Elisa (EIA) test is performed first, and is less expensive (\$6 for negotiated contracts--i.e. Damon Corp. contract with the military, \$48 for individuals). If a positive result is obtained on the EIA, a "Western Blot" is performed (at \$50-121 per test). Marketdata estimates that this segment constitutes a \$67 million annual potential.

Blood Cholesterol testing represents a **\$1.5 billion annual market**. Recent media coverage of health problems related to bad diet patterns, and suggestions of testing from government agencies such as the National Institute of Health (NIH) may propel this test market to the \$3 billion level in the near future. About 100 million blood cholesterol tests were performed during 1987.

Pap Smears, important tests for predicting cervical cancer in women, are estimated by Marketdata to constitute a market in the range of \$720 million to \$2.1 billion per year. This is based upon the CDC and National Cancer Institute's estimate of 60 million Pap tests performed annually. Lab charges typically run \$12 per test, but private doctors may mark prices up to \$35--consequently the range from \$720 million-\$2 billion.

Employee Drug Abuse Testing is estimated to become a \$160 million market by 1990, with about 713,000 work place drug tests administered during 1985. Commercial labs are estimated to handle 30% of this market, military screening takes another 27%, hospital labs-16%, and on-site testing-14%. Activity is highest in federal agencies right now, especially transportation fields affecting the safety of the public. Due to rebellions by many employees in the private sector, claiming violation of privacy rights, this segment will probably grow slower than the others above, and progress is likely to be slow.

STRUCTURE OF THE INDUSTRY

There are between 4,500 and 6,000 independent commercial clinical test labs in the United States, depending on which source is consulted. The

national Yellow Pages lists the higher number, but official government statistics of 4,000-4,500 are probably closer to the real number, since Yellow Pages listings may contain a substantial number of labs no longer in business. California has more than twice as many labs as any other state, over 1,100, followed by New York State with 436, Texas, Florida, and Ohio with over 300 each.

In addition, there are almost 7,000 hospitals in the United States, the majority of which are community or non-federal types. Clinical labs come under the "ancillary services" department of these hospitals.

There were over 11,000 federally registered clinical labs in 1987, including 4,368 Medicare-approved independent labs and 6,658 Medicare-approved hospitals, the vast majority of which have at least a small emergency lab.

The fastest-growing area is physician-office labs, or POLs, estimated at between 50 and 100,000.

The government's Census data (1982 is the latest available until the 1987 Census figures are released) combines **medical and dental** lab economic operating data. In 1982, more than 60% of such labs were classified as corporations, vs. 28% as proprietorships and 10.7% as partnerships. Marketdata feels that the percentage of corporate labs has increased since 1982, based on recent trends in the industry, and its more competitive nature.

For these labs, **payroll costs** averaged almost 40% of sales, they typically employed 8.5 workers, and 86% were classified as **single-unit** labs. **Multi-unit** facilities represented only 14% of the number of labs but captured 43% of total receipts.

From 1983-87, **operating expenses** remained stable or declined slightly, representing 89.3% of sales, leaving a 10.7% **operating profit**. However, pre-tax profits have been eroded to 6.7% of sales, due to higher "all other expenses". **Debt** loads increased significantly during 1987, and lab owners seem to be taking much more money out of the business for their personal compensation. This ratio rose to 16.7% of sales in 1987, compared to 9.8% only two years earlier.

MARKET AND COMPANY DEVELOPMENTS - INDUSTRY CONSOLIDATION

Six large regional/national laboratory chain operators control at least 30% of the market, and an estimated 52% of the \$2.4 billion national "reference lab market. They include the following companies.....SmithKline Bio-Science Labs (\$372 million in 1986 sales), Roche Biomedical (subsidiary of Swiss parent Hoffmann LaRoche--\$255 million), MetPath (Corning Glass Works--\$215 million), National Health Labs (Revlon Group--\$189 million), International Clinical Labs (recently acquired by SmithKline--\$168 million), and Damon Corp. (\$98 million).

On April 14, 1988, Corning Glass Works agreed to drop out of a bidding war with SmithKline Beckman Corp. for International Clinical Labs, by selling its stake of 3 million shares for \$26 each (taking a \$33 million profit in the process). Corning had hoped to double its sales in the testing business via the acquisition, giving it market share parity with SmithKline as the industry leader.

The next most probable acquisition candidate should be the Damon Corp. of Needham Heights, MA. A near 10% stake was acquired recently by American Magnetics Corp. in April 1988. Damon is attractive because of its profitability, strong sales and earnings growth, joint ventures with large hospitals, vertical integration into the field of disease diagnosis and instruments, and 63% ownership in a biotechnology unit. In addition, it has the government military contract for AIDS screening. Damon is also the last major independent clinical lab company.

Industry consolidation should continue into the near future, as small "mom and pop" independent labs' ranks thin with the keen competition and pricing. As confirmed by Marketdata's March/April 1988 national phone survey of Lab Directors, small labs cannot compete with the large chains on price and volume, and can't afford the expensive capital outlays for the new generation of automated analyzers that do very high-volume testing at rapid speeds.

An issue that **no one** in the clinical laboratories industry is currently talking about, but which Marketdata feels could have a significant effect over the long term, is that of **the increasing vulnerability of the United States' service sector to foreign competition.** A March 21, 1988 Wall Street Journal article pointed out that: "...the U.S. advantage in services could fall victim to some of the same problems that have plagued manufacturing: preoccupation with short-term profit, inattention to

detail, alienated workers, and emphasis on cost savings at the expense of customer convenience."

These words are hauntingly familiar when examining the current problems characteristic of the clinical lab testing industry.

European companies are penetrating the U.S. market in an increasing range of businesses, such as employment services (Blue Arrow PLC of Britain acquired Manpower Inc.), office cleaning (ISS AS of Denmark ranks among top U.S. firms with \$220 million in revenues), cheaper data entry services by Caribbean firms. And, observers see parallels between recent advances by the **Japanese** into the service sector and earlier pushes into auto and semiconductor markets, initially targeting high-volume, low margin areas, then moving into more lucrative areas later on.

It would not surprise Marketdata to see the Japanese or Europeans move into clinical lab services in the future, either through outright buy-outs or the establishment of competing chain operators.

CRITICAL INDUSTRY ISSUES & COMPANY STRATEGIES FOR SURVIVAL AND GROWTH

INDEPENDENT COMMERCIAL LABS

Marketdata's April 1988 phone survey of Lab Directors nationwide revealed that.....

* Finding and retaining qualified lab workers (technicians, cytologists, supervisors, etc.) is their most critical problem currently. Declining enrollments in college programs create a shrinking labor pool to recruit from. Workers are increasingly afraid of contracting AIDS, are dissatisfied with salary levels not commensurate with their training and perceived job risks. Many professionals are leaving the field entirely, and the situation is very much like the current nursing shortage.

* Coping with lower Medicare reimbursement fee schedules and DRG-imposed budget cuts is the second most important concern. This is a major factor in determining whether independent labs can continue to provide quality service and good quality control for Medicare patients.

* Labs are very concerned about the totally unregulated physician office labs, not only from a lost business standpoint, but because they feel that most doctors do not have the time or training to implement proper

maintenance/quality control procedures to ensure accurate test results. Right now, they are accountable to no one, and may charge whatever they decide. Most directors feel that the decision to do their own testing is based on the potential for increased income, rather than faster turnaround time or more accuracy.

Most Lab Directors believe that new POL federal regulation and inspection legislation is imminent and critically necessary to restore public faith in the industry overall. A majority report losing some small amount of test business to physicians, but not enough to worry about. Doctors are mainly performing CBCs, glucose, and blood cholesterol tests--but not the more complex hormonal and therapeutic drug studies. They *are* performing a fair amount of chemistry profiles, however.

* The overwhelming majority of directors are confident in the reliability and accuracy of lab instrumentation today. They are satisfied with the new generations of analyzers, which, by nature must produce a minimum of downtime due to the life-or-death end-user applications in hospitals. Instruments today are more sophisticated and user-friendly, but also more sensitive and dependent upon proper calibration, user training, and use of the right reagents and supplies than ever before.

RECOMMENDED STRATEGIES FOR INDEPENDENT LABS

* Restore public confidence in the accuracy of such popular lab tests as Pap smears, cholesterol tests, urine drug tests and others by maintaining a rigorous quality control program, and documented record of ongoing inspection of the lab by federal/state agencies. This is especially critical in states which do **not** require lab worker proficiency tests. Actively promote the lab's record of accuracy and quality service, if at all possible (via a "capabilities brochure" or other literature, prominent display of any awards or certificates of achievement, etc.).

* Obtain state/city licenses to perform AIDS testing, to take part in this high-growth market of the next 5-10 years. Develop strategic plans to go after and obtain this test business, so that when the blood bank/state health department system becomes overloaded, you are ready and set up to accept this business, if you want to.

* Avoid head-to-head price wars and high-volume testing that pits you squarely against the six large chain operators. Offer superior local service instead, based on geographic proximity to doctors and patients, and rapid (same day) turnaround service--**without** compromising quality.

* Carve out a market "niche" by establishing a specialty test area, if you have not already (i.e. radioactive tests, infertility, etc.). By doing so, you limit the chance of encountering substantial competition from POLs in the routine test area--a segment that physicians are likely to encroach upon more and more in the future.

* **Recruitment of *new*** workers is probably the most difficult task for labs today, and there is no easy solution. It is very similar to the nursing shortage, where hospitals have had to boost salaries substantially, recruit from overseas nations, and create a new attitude about treating nurses with the professional respect and recognition they deserve. The same is true for labs. They will be forced to pay higher salaries, or to find foreign-born workers who perhaps have not been in the U.S. for a long time, that will accept pay scales U.S. technicians will not.

Until the AIDS hysteria abates, it will be very difficult for labs to convince new workers that all possible precautions have been taken to ensure their health and safety. If rubber gloves, masks, and other protective garments are used, make sure they are the **best quality** on the market. No compromises will be tolerated by lab staffers in this area.

Indeed, these higher salaries and benefits and protective measures will hurt the bottom line profitability of small labs in the short run, but is there really any alternative? Without technicians, tests cannot be performed--instruments cannot totally automate a lab's business. It is an investment in the lab's **long-term** viability.

* Retain more ***existing*** staff by: giving them more incentives to stay on the job--profit sharing plans, contributory savings/retirement plans (401Ks), rewards for productivity gains **and** long-term reliability and accuracy records, bonuses for staying with the company for a full year (may ask them to sign an employment "contract"), a tightly-monitored AIDS infection protection program, rewards for efficiency suggestions that result in improved lab operations and performance, more holidays/time off, etc.

* Educate patients about the risks inherent in lab procedures performed at **POLs**, explaining why the larger independent lab has more sophisticated capabilities (instrumentation), more highly trained workers with more years of training and certification, experience with reagents and proper test techniques, etc. Point out that POLs are **not** federally regulated. Develop a flyer or brochure for hand-out in the office. Write a brief story for local community newspapers/journals, explaining the situation.

- * Write a detailed, well thought out strategic **Marketing/Survival Plan**-involving management **and** technicians. This should be a yearly plan, which, according to changing market conditions and competitive actions, is adjusted and updated as needed. The plan will force lab directors to think about the interim steps/actions required to achieve long-term objectives, in a coordinated and formal fashion. Contingency plans and the timing of various company actions should be part of the plan.

STRATEGIES USED BY IN-HOSPITAL LABS

Some of the main methods used by in-hospital labs to cope with the more competitive environment today, resulting from the DRG system imposed in 1984 plus competition from commercial and physician office labs, include the following.....

- * Marketing Plans developed to market outpatient testing
- * Installation of automated instruments and microcomputers
- * Competitive bids from reference facilities
- * Volume discounts - joining other hospital labs in group purchasing
- * Market segmentation: industry, HMOs, public
- * Price discounts
- * Regulation of test ordering by clinicians
- * Mergers with other labs

- 15 -

THE CRY FOR FEDERAL REGULATION - INDUSTRY CRITICISMS OF PAP AND CHOLESTEROL TESTS, AND THE GOVERNMENT RESPONSE

PAP SMEAR TEST INACCURACIES

The Pap smear has become one of the most common laboratory tests in America. It is also one of the most inaccurate. The Wall Street Journal (Dec. 29, 1987) reported that studies show that the Pap test fails 20-40% of the time to detect cervical cancer or precursor cell abnormalities, making it one of the most inaccurate of all clinical laboratory procedures. Each year, an estimated 60,000 women develop the disease. Much of the blame for the high failure rate rests with labs that fail to detect abnormal cell growth in screening the tests.

The picture is of a Pap screening industry kept alive by overworked, undersupervised, poorly paid technicians. It is an industry that often ignores the few laws that exist to protect women from slipshod testing. Across the country, high-volume, cut-rate laboratories, sometimes called Pap factories or Pap mills, allow technicians to analyze up to four times as many specimens per year as medical experts recommend for accuracy. Many of them pay screeners on a **piecework** basis which encourages them to rush the analysis. Some technicians work at two or three jobs, earning as little as 45 cents to do the key analysis on a test that may cost patients \$35.

Even more surprising is the fact that labs often let employees take slides **home** to screen. "Pap mills" thrive by underbidding competing labs, charging as little as \$1.50 per test. They are sought out by some gynecologists, who profit by marking up lab fees on patient bills. These bargain fees also appeal to budget-conscious administrators of group health plans and government-funded clinics.

Nearly 50% of the lab errors apparently result from inadequate cell specimens obtained by physicians or other health-care professionals, according to the American College of Obstetricians and Gynecologists (or ACOG). Alan Ng, a leading pathologist, surveyed the quality of Pap testing in the U.S. in the late 1970s, and reported finding a "serious defect" in physician techniques. Specifically, there was a failure to sample enough parts of the genital tract. Myron R. Melamed of New York's Memorial Sloan Kettering Cancer Center believes that students were better trained in Pap testing during the 1950s and 1960s. Now, these tests receive less attention.

In many cases, Pap test errors made by physicians should be caught by laboratory workers and the pathologists who supervise them. Many labs are reluctant to send unsatisfactory specimens back, out of fear of losing a physician's business. The physician who gets a sample back can either ignore it or admit an error and call the patient back for another visit. There is a natural reluctance to do this.

Compounding the problem is the communications between the doctor and the lab, which may be impaired when physicians, seeking bargain prices, send specimens hundreds of miles away for analysis. This was the finding of a 1980 report issued by a National Cancer Institute panel of experts. The use of such labs by physicians has increased in recent years.

Some labs attempt to help doctors by giving them monthly grades on their Pap specimens. They report that "....the good ones want to know how they are performing. They seek feedback."

Heightening the urgency of the problems with Pap tests is the fact that some doctors now believe that cervical cancer develops faster than previously thought. Also, they see it turning up in more young women.

Unlike some kinds of medical tests, Pap smears aren't checked by chemical or mechanical means but depend on human visual examination of the specimen. It is tedious work and, if done properly, time-consuming as well. Accordingly, the American Society of Cytology recommends that no full-time "cytotech" examine slides from more than 12,000 patients per year. But, this limit is blatantly ignored.

For example, Kyto Diagnostics Inc. of New City, N.Y., a large private lab, reported average workloads of 35,000 cases per screener per year in 1986--nearly three times what the cytology society thinks is safe! Even as Pap smear volume is rising, the number of qualified screeners is falling. Nearly 50% of the schools that train cytologists have closed in recent years, and nearly half of advertised positions for cytotechs in California remain unfilled.

To cope with the labor squeeze and lower their costs, labs are turning increasingly to piecework. Even labs with salaried cytotechs, such as Metpath, usually let them do extras on a piecework basis. And, labs frequently let workers leave for the day as soon as they reach their quotas--another incentive to screen slides as rapidly as possible. Piecework pay scales also encourage overwork--50 cents per slide.

THE STATE & FEDERAL RESPONSE TO THE PROBLEM

Only one state, California, even attempts to prevent workload abuses. Its law says that "no cytotechnologist shall be required to examine more than 75 one-slide gynecologic cases, or 50 two-slide gynecologic cases per day." But violation is rampant. **The biggest Pap lab in the nation, Cancer Screening Services, of North Hollywood** (a unit of American Cyto Genetics), processed almost a million Pap cases in 1986.

The only equipment needed for Pap screening is a microscope. The Pap test is the only common lab procedure for which federally-licensed labs need not undergo periodic proficiency tests. Only one state, New York, requires screeners to pass such tests. The largest group overseeing commercial labs, the College of American Pathologists, doesn't set any overall workload limit.

One lab that has come under scrutiny is International Cancer Screening Laboratories in San Antonio, Texas. Among the largest in the nation, ICSL processes about 500,000 slides annually from 49 states. In 1985, it was banned from operating in New York after failing the state's proficiency test in cancer screening.

In Oklahoma, a different lab to screen Pap tests can mean very different results. During the late 1970s lawmakers voted not to finance a free Pap smear program. Women protested vigorously, however, and the state caipital reversed its decision. Intent on reducing the program's cost, the state health department in mid-1986 stopped sending Pap smears to be analyzed by its longtime contractor and began awarding one-year contracts to the lowest bidder.

For years, "abnormals" consistently came in at 7% to 9% of the total Pap smears analyzed. The new contractor, Northwest Laboratories Inc. in Oklahoma City, reported only 3.5% abnormals. Four months after the contract ended, the state still hadn't re-screened any significant number of slides to determine their accuracy. Northwest Labs, declining to be interviewed by Wall St. Journal staff, won the contract for the 12 months in question with a bid of \$1.50 a slide. The bid from Oklahoma Teaching Hospitals, the old contractor, was more than twice that.

But, the state did not follow up on who actually performed the screening. Northwest, it turns out, was so understaffed that it farmed out some of the work, to a cut-rate lab in Texas.

Jack Painter, the manager of the anatomic pathology lab at Oklahoma Teaching Hospitals, says that **previous screening programs cut the number of deaths from cervical cancer and that now he fears death rates may go back up.**

A top U.S. health official has called for testing the proficiency of Pap smear lab workers (Wall Street Journal, March 11, 1988). Dr. William L. Roper, administrator of the Health Care Financing Administration, made his comments after witnesses told a congressional subcommittee that **doctors often choose labs for all types of medical tests based on availability of kickbacks rather than quality of services.**

Dr. Roper stated: "We will soon report comprehensive regulatory reform to address the major quality issues" in Pap testing and other lab work. In earlier testimony, Richard P. Kuserow, inspector general for the health department, said his office was "seeing a **nationwide proliferation of allegations of kickbacks, fraud and poor testing by laboratories**". James Shannon, Massachusetts attorney general, reported finding numerous cases of physicians accepting kickbacks from labs for channeling business to them. Some labs were found to be paying salaries of physicians' office staff, and other offered shares in their businesses, with dividends based on the volume of business the physician referred.

Mr. Shannon also described how labs charged **two** sets of prices, one for governmental beneficiaries and another for other customers. Evidence exists that labs are doing this on a nationwide scale, and Mr. Shannon asserts that many states have weak anti-kickback laws. "The system needs reform.", stated Mr. Shannon. One of the industry's most persistent critics is Rep. Ron Wyden (D. Ore.), who noted that the Health Care Financing Administration in the early 1980s had cut its lab inspection staff by 30%. He therefore blames much of the problem on the Reagan Administration.

Finally, it is often impossible to determine exactly what went wrong in faulty Pap smear diagnoses. One cytotech, a consultant to a national laboratory, says that her lab's lawyers instruct workers to "get rid of slides as soon as possible" to limit liability." Even if a suspect slide exists, retrieving it can be a problem.

The dimensions of the problem are enormous. A Mansfield, Ohio lab in the late 1970s was discovered to have sent out nearly 6,000 erroneous Pap test reports. It is a major concern for such organizations as the Planned Parenthood Federation of America, which in 1986 took 1.4 million Pap smears through affiliated offices and clinics.

LAB PERFORMANCE & REGULATION INVESTIGATIONS BY WRC-TV IN WASHINGTON, DC

The Clinical Laboratory Management Association recently reported on a series of reports aired on the NBC-TV affiliate WRC-TV in the Washington, DC area. It was this report that drew the quickest responses from key members of Congress, the Washington, D.C. City Council, and the state of Maryland.

Representatives Ron Wyden (D-OR), Congressman John Dingell (D-MI), and David Durenburger (R-MN) are all looking at the issue of laboratory regulation. The series criticized the lack of state and government regulatory controls in labs in Washington, D.C., Virginia, and Maryland. The four-month study of clinical labs on the East Coast was entitled: "Deadly Mistakes", and it indicted government regulations of laboratory work as spotty and full of loopholes.

Among the report's findings.....

- * Nearly 50% of all medical labs in Maryland and DC could not show adequate performance of quality control procedures or adequate testing of equipment.

- * **New York is the only state currently testing the accuracy of the people in the labs who read Pap smears.**

- * 60% of all lab work done in the U.S. is performed in private physicians' labs, and test results from those labs are more likely to be erroneous due to faulty equipment and untrained personnel.

- * More problems occur with Pap smears than with any other test; the error rate was cited at 20-40%.

- * All hospital labs in the District of Columbia area are inspected; all commercial labs are inspected in Maryland and the district, but in Virginia, only labs that do Medicare or interstate work are inspected--leaving an estimated one-third of the commercial labs in Virginia uninspected.

Increasingly, testing is moving away from hospital labs and into the physician's office. Government statistics reveal that 60% of all lab testing is currently performed in physician's offices.

In the Washington, D.C. area alone, more than 30,000 physicians operate private labs in their offices. Less than 1% of these labs are inspected or regulated. Inaccurate or faulty laboratory equipment often produces erroneous test results--the calibration of machines can be off, the age or temperature of chemicals can alter results--but **the biggest threat to accurate lab testing is human error. Careless, untrained, or tired technicians often misread, misinterpret, or switch test samples.** In one study done in the Washington, D.C. area, it was revealed that 38% of the people doing lab work in private physician's offices may have no laboratory training at all.

Dr. Jocelyn Hicks, Head of Laboratory Medicine at Washinton's Children's Hospital, recently surveyed area physicians and found that only 13% employed registered medical technologists--with the remaining people performing tests being receptionists, technicians, nurses, or physicians. Furthermore, a study in Illinois looked at a wide variety of procedures, and found that labs with certified technicians were 95% accurate, while those with noncertified personnel were only 75% accurate.

CONGRESS COMPLETES ACTION ON 1988 BUDGET PACKAGE--SUBSTANTIAL LAB CUTS ARE INCLUDED

During the first three months of calendar year 1988, lab payments will be frozen at the levels in effect on December 31. On April 1, 1988, hospital outpatient testing will become subject to the same fee schedules that apply to all other Part B clinical lab testing. The 1.4% CPI update will be eliminated for 1988. And, fee schedule rates for the following procedures will be reduced by 8.3%.....

automated panels	sedimentation rate
cholesterol, blood	blood sugar (glucose)
complete blood count	urinalysis
hemoglobin	blood uric acid
hematocrit	blood urea
prothrombin time	leukocyte count

Laboratories located in states where the fee schedule rates are above the medians for most tests will feel the effects of these cuts most severely. Congress felt that the bulk of the savings should be obtained from those labs located in states where the Medicare payment rates are high.

Also, effective January 1, 1990, high-volume physicians' office labs

will be treated as independent laboratories and accordingly will be subject to regulation. High-volume is defined as any POL or group practice lab that performs more than 5,000 tests per year.

One provision of the law requires the GAO to study the fee schedules to determine whether they are set at appropriate levels. In conducting the study, the GAO is directed to analyze lab costs and revenues. Suppliers of lab tests are required to open their books to the GAO, with failure to cooperate leading to exclusion from the Program.

Under the new law, the Health Care Financing Administration is again barred from implementing its competitive bidding demonstration. This year's moratorium will last until Dec. 31, 1988.

"...it is likely, when all is said and done, that many laboratories will be paid less than they were on November 20."

CHOLESTEROL TEST INACCURACIES

A government panel's recent urging that all adults have cholesterol levels tested could boost spending on tests to \$3 billion a year from \$1.5 billion now, says industry newsletter Health Business. Beneficiaries would include such equipment manufacturers as Abbott Laboratories, Beckman Instruments Inc., and Eastman Kodak. Abbott personnel feel that cholesterol testing will probably double. Cholesterol-reducing drugs are also expected to benefit, with people taking them almost prophylactically. Use of these prescription drugs will in turn spur demand for testing to determine whether the treatment is working, and doctors will earn more as people diagnosed as having high cholesterol return to be retested.

But, while heart researchers publicly urge cholesterol tests, they privately worry that their battle against heart disease is being undermined by inaccurate or misleading lab tests.

When a physicians' group in 1985 asked 5,000 of the nation's top laboratories to run cholesterol tests on identical samples, nearly half produced results that a leading expert calls "unacceptable". Some labs weren't even close. In the test, the College of American Pathologists sent each lab a sample with a known cholesterol value of 262.6 milligrams per deciliter. The labs came back with reports ranging from 101 to 524.

The National Institutes of Health reached a consensus that 50% of adult Americans have levels high enough to worsen their risk of heart disease. **About 100 million blood-cholesterol tests were performed in the U.S. last year**, at a cost to patients and insurers of between \$1 billion and \$1.5 billion. Already it is among the most common clinical laboratory procedures.

Without accuracy in these tests, however, treatment is problematic. Patients who falsely test low may skip diet or drug regimens that their doctors otherwise would prescribe. Patients who falsely test high may face the unpleasant side effects of cholesterol-lowering drugs, to say nothing of an unnecessary cost of up to \$125 a month.

Why are tests faulty? Lab experts say some companies scrambling for a share of the growing market for cholesterol-measuring devices are selling machinery they haven't taken the time to calibrate precisely. Further, the people doing the tests may use equipment incorrectly, or they may buy chemical supplies not meant for their model of analyzer. And physicians may not properly interpret test results, in part because some lab reports include outdated information on what is "normal".

Many commercial and private labs--even medical centers--have as much as a 20% margin of error. One lab owned by Swiss-based Roche Biomedical Laboratories Inc., according to the Wall Street Journal (Feb. 3, 1987), was 24% too low on a 1985 test sample. But another lab owned by the same company was 42% too high, state records show.

In tests for overall cholesterol level, some of the skewed reports are believed to result when a lab uses inappropriate chemical "reagents". In their marketing activities, analyzer manufacturers occasionally discount the machines themselves, intending to make up the lower price through sales of reagents. But, personnel at New York State's clinical chemistry laboratory say that labs sometimes cut costs by buying less-expensive reagents not designed for their model of machine.

Labs often confuse doctors by noting in their test reports whether the cholesterol level is "normal". These normal ranges differ widely, and can run as high as 330--far above what cholesterol experts agree is safe. Labs commonly use the reference range supplied by the maker of their testing equipment. However, many manufacturers don't base the range on established links between cholesterol levels and coronary-artery disease.

Some testing problems may result when equipment performs well in factory tests but poorly in the field. Of particular concern are the newer, cheaper models, typically called "black boxes". These are aimed at physicians' offices, and can cost as little as \$5,000. Many in the medical world welcome such devices. A physician who has his own cholesterol analyzer can bill for the test instead of passing the work on to a lab. But, quality varies widely among these analyzers.

There is more than one way to measure cholesterol. More than 30 different machines are currently sold, using somewhat different chemical processes. The Beckman Astra 8 analyzer, for example, had an average margin of error of 27%. A major cause of inaccuracy, scientists say, is the sale of poorly calibrated instruments. Proper calibration is time-consuming. Experts say: **"If physicians don't demand accuracy--and by and large they don't--then manufacturers lack the incentive.** Manufacturers needing help with calibration can get it from the CDC and the National Bureau of Standards. But, CDC personnel such as Dr. Cooper cite a limited response so far.

There is a need for manufacturers to agree on a "standardized protocol" to ensure that different machines produce the same results, through such an organization as the Health Industry Manufacturers Association. The NIH panel investigating cholesterol testing hopes ultimately to reduce the error rate to 3% or less.

FEDERAL AND CORPORATE DRUG TESTING PROGRAMS **A STATUS REPORT**

SIZE AND NATURE OF THE MARKET

Standard & Poors, in its April 1987 Health Care Industry Survey, estimated that the market for drug abuse testing was worth \$115 million during 1986 (\$80 million in the U.S.). It has been spurred by the adoption of mandatory drug tests for job applicants and employees of large corporations and government agencies. More than 30% of the Fortune 500 companies in the spring of 1987 administered mandatory drug testing programs, and the U.S. military administers more than 3 million tests per year.

Based on a study by Boston Biomedical Consultants, the drug abuse testing market was divided by major end-users as follows.....commercial laboratories - 30%, military screening - 27%, hospital labs - 16%, on-site testing - 14%, and international - 9%. The major manufacturers' market shares were estimated as follows.....Syva (a unit of Syntex) 55%, Hoffmann-LaRoche 27%, Marion Hoffmann-LaRoche 27%, Marion Laboratories 8%, and all others 10%.

DRUG TESTING OF FEDERAL WORKERS

Drug testing of federal workers is starting to gain momentum. About 20 agencies will begin tests soon, covering 30,000 employees this year. All workers at agencies such as the **Drug Enforcement Administration** and the **FBI** will be subject to random checks, but only about 10%, the "critical" force, will be targets at most other agencies. The Custom Service has tested 3,725 job and promotion candidates since last April.

The Transportation Department has given 720 random tests in five months, with five positive results. It plans 15,000 tests a year, hoping to become a federal model. However, federal workers' unions are fighting the trend, with minimal success so far. One union spokeswoman predicts that "The Supreme Court will decide the issue, one way or the other."

CORPORATE DRUG AND AIDS TESTING PROGRAMS

Seven states have passed laws restricting drug tests. Random testing in private industry is under legal attack, and the Supreme Court has agreed to decide whether testing government employees violates the Fourth Amendment. Employees with AIDS are covered by laws protecting the

handicapped. But few companies have educated their workforces to prevent discrimination by co-workers.

Today, Americans are asserting the right to be left alone. Individual employees and unions are filling court dockets with challenges to random drug testing. AIDS patients are suing employers for breach of confidentiality when co-workers learn of their condition. States Paul Saffo, an expert on information technologies with the Institute for the Future: "After health care, privacy in the workplace may be the most important social issue in the 1990s."

Drug use costs American industry nearly \$50 billion annually in absenteeism and turnover, estimates Business Week. In the lawsuit-happy 1980s, failing to ensure a safe and drug-free workplace can subject an employer to millions in liability claims when people are injured by an errant employee or faulty products.

Some 30 of the nation's largest employers (such as IBM, AT & T, and Johnson & Johnson) have endorsed a 10-point bill of rights on AIDS issues. It calls for education to dispel fears, urges that medical records be kept confidential, and pledges not to test for the AIDS virus in hiring.

Although screening of new applicants is up, companies may be cutting back on the most controversial--random tests of current workers without reasonable cause. Six of the seven states with laws on drug testing allow random tests only for workers in hazardous and safety-related jobs. Utah is the only exception. **A 1987 American Management Association survey of 1,000 companies showed that 34% had a drug-testing program, up from 21% in 1986.**

Even though testing has mushroomed into a \$1 billion industry, there are no standards for handling laboratory samples. "It's very easy to set up a poor lab, but not so easy to set up a good one," according to Richard L. Hawks, chief of research technology at the National Institute on Drug Abuse.

While labs used by federal agencies will soon be required to meet minimum standards, private employers can use anyone--and that's a big problem. The error rate for urinalysis can be as high as 40%, according to industry consultants.

Laws in a few states allow testing *only* if an employer has reason to suspect impaired job performance. Rhode Island's law requires companies that test to have a drug counseling program.

Testing for drugs can cost from \$15 to \$45 per exam. With the threat of large jury awards figured into the picture, companies may have to look more closely at the trade-off between their own peace of mind and that of their employees. **The Employment Management Association reports that one in three companies considers drug testing but decides against it, chiefly out of fear of getting sued.**

URINE DRUG TESTS - THEIR ACCURACY & RELIABILITY

The area of corporate and government drug testing of employees, via **urine** samples, is controversial and is being challenged as an invasion of individual privacy. The accuracy and reliability of these tests is of paramount importance if companies and government hope to convince employees that compliance is in their best interest.

The primary purpose for instituting urine drug testing in the workplace is to deter drug use and thereby prevent adverse impact of drug abuse on worker safety and performance. The more worker performance affects the public safety, the greater the impetus for, and acceptance of, mandatory testing. This is the case, for example, in occupations affecting public transportation, and in particular, travel. Other justifications for mandatory testing in the workplace are used, such as detecting and deterring drug abuse off the job but which may affect worker performance, and detecting and deterring behavior that is illegal. However, there is profound disagreement on the appropriateness of mandatory drug screening as a condition of employment as the means to meet these objectives.

The following information was taken from the testimony of Lawrence Miike, Office of Technology Assessment, U.S. Congress. The testimony took place on May 20, 1987, before the House Committee on the Post Office and the Civil Service Subcommittee on Human Resources.....

Existing urine drug screening tests are highly accurate and reliable, provided that: 1) initial positive results are confirmed by a separate test that is based on different physical and chemical principles from the initial screening test, and 2) appropriate lab procedures are used. The most important technical issue at the moment is whether these tests are being performed properly. There is more chance for error in mass testing.

To minimize errors associated with testing, it is necessary to test the testers themselves. Such "proficiency" test programs are conducted at several levels. Within the laboratory, lab management may slip in known test samples with actual specimens to see how well technicians perform when they do not know which specimens are test samples. At another level, tests of individual labs can be conducted by outside monitors. For example, several national organizations provide proficiency testing services for a fee.

The use of **urine** drug testing is already a compromise between available technologies and the objectives of screening programs. If the objective is

to detect drug abuse at the workplace, **blood** drug tests would be the technological choice, because detectable drug levels in blood mean that the person being tested has used the drug very recently. But blood testing is considered too intrusive, and too costly. Urine drug tests, while less physically intrusive than blood drug tests, are arguably more intrusive, since one has to urinate on demand in the presence of a person whose sole purpose is to see that you do not cheat.

Hair analysis is being touted as a possible new screening technology that is less intrusive than urine testing. However, this method will uncover drug use that is even less correlated to recent use than urine testing.

Other potential problems include the fact that many non-drug users are subject to testing, and **other** substances in the urine specimen may react with the test ingredients (the "false positive" issue). Also, as a test is calibrated to detect smaller and smaller amounts of a drug, the chances increase that the test ingredients will also react with other substances in the urine.

There is even great variability in existing drug screening programs within the Federal government (see chart in this section on Drug Testing in Federal Agencies).

The tests commonly used in urine drug screening programs are based upon one of four methods: three types of immunoassay and thin layer chromatography (TLC).

Proficiency testing of labs that perform drug testing has revealed severe deficiencies over the past 10 years. Actually, most of these shortcomings have been in not being able to identify positive samples rather than in identifying negative samples as positive. Some of these errors have been attributed to "sink testing" or throwing away a sample and reporting it as negative. The error rates as published in the literature have improved as tests and lab experience has improved, but some level of error is to be expected, especially when these tests are being conducted on large numbers of people.

The proficiency testing program established under the **Clinical Laboratories Improvement Act of 1967** and conducted by the Centers for Disease Control was discontinued as of September 30, 1986. Furthermore, for a number of years CDC's principal involvement had been in clinical testing, not in proficiency testing of drug screening programs. Only a handful of States have such proficiency test programs. Several

professional associations offer proficiency testing, some manufacturers of the test kits offer a form of proficiency testing, some Federal agencies have their own proficiency test programs, and private firms have increasingly entered into this test business.

In recognition of the increase in drug testing programs and the lack of uniform standards to ensure the credibility of the results of labs conducting the analyses, the National Institute of Drug Abuse (NIDA) was devising lab accreditation standards which were to be implemented in early 1987. The standards incorporate measures to help ensure analytic accuracy and adherence to appropriate forensic procedures such as "chain of custody".

Prerequisites to lab accreditation would include:

1) evidence of adequate performance in an established "blind" proficiency test program and ongoing participation in such a program, 2) the existence of sufficient onsite resources with which to conduct both screening and confirmatory testing; 3) appropriately trained directors and supervisors of lab services; 4) the presence of an internal quality assurance/quality control program; and 5) submission to pre-accreditation and periodic post-accreditation inspections. The NIDA standards should have been finalized in early 1987 and once labs have had the opportunity to generate proficiency testing scores, the accreditation process will begin. Although the program will be voluntary, NIDA will maintain a list of accredited labs that will be offered to employers planning to implement drug testing programs.

Proficiency testing of clinical labs has been offered by five major programs; the American Association of Bioanalysts (AAB), the College of American Pathologists (CAP), the American Society of Internal Medicine (ASIM), the American Association for Clinical Chemistry (AACC), and the Centers for Disease Control. However, proficiency testing of urine drug screening is currently offered by only three associations.....AAB, CAP, and AACC.

As for emerging new areas of screening, monoclonal antibody-based assays tests have recently been developed by Roche Diagnostics. In fact, over the past 10 years, approximately 100 new diagnostic tests using monoclonal antibodies have been approved by the FDA. The use of systems based on fluorescent labels (by Abbott Laboratories) will probably also be expanded. Efforts are also underway to make mass spectrometry more economical. Other types of biological samples, including blood, hair, and

saliva, have been proposed as alternatives to urine drug screening. Although blood tests potentially provide a more specific indication of drug impairment, such analyses generally require more sophisticated techniques and more invasive sample collection than is the case with urine testing.

THE MEDICAL LABORATORIES INDUSTRY

DRUG TESTING IN FEDERAL AGENCIES - 1986

	<u>ARMY</u>	<u>AIR FORCE</u>	<u>NAVY</u>	<u>FAA+</u>	<u>SECRET SERVICE</u>	<u>CUSTOMS SERVICE *</u>
Amphetamines	-	*	*	*	*	*
Barbiturates	-	*	*	-	*	-
Marijuana	*	*	*	*	-	*
Cocaine	*	*	*	*	*	*
Methaqualone	-	-	-	-	*	-
Opiates	-	*	*	*	*	*
PCP	-	*	*	*	*	*
LSD	-	-	*	-	-	-
<u>Others</u>						
Quinine	-	-	-	*	-	-
Pain killers	-	-	-	*	-	-
Tranquilizers	-	-	-	*	-	-

+ FAA + Dept. of Transportation's Federal Aviation Admin.

* Dept. of the Treasury

* Currently testing

- Not currently testing

SOURCE: Subcommittee on Civil Service, House Post Office and Civil Service Committee, February 1986

AIDS TESTING - A STATUS REPORT

Currently, an estimated 1.5 million people in the United States are infected with the AIDS virus. AIDS has now been found in every state and in almost every foreign country. A person with AIDS will incur between \$40,000 and \$140,000 in medical bills from diagnosis to death. By 1991, just ten years after the first reported cases of AIDS in the U.S., AIDS will exceed automobile accidents as the leading cause of death. In 1991, an estimated 145,000 patients with AIDS will require health and support services that will cost between \$8 billion and \$16 billion.

The business world, for the most part, has not yet addressed the problem. A poll conducted in March 1987 of 600 senior human resources executives by Louis Harris and Associates found that 89% of the respondents had no specific policy for dealing with employees who had AIDS.

If employers require preemployment or current physical exams that include the AIDS blood test, such physicals must be required of all potential or current employees. It is considered discriminatory to request tests of selected individuals. Moreover, physical exams should include tests for conditions *other* than AIDS.

At this time, **insurers** are prohibited from excluding AIDS coverage in their policies. Some insurers, however, are requiring the applicant to take a test as a prerequisite for some types of personal and life insurance, but some cities and states have banned the practice completely, after cries of protest from the gay community.

The very accuracy of AIDS tests is under close scrutiny, by Congressional committees. The following information about **AIDS antibody testing** was extracted from the October 19, 1987 testimony of Lawrence Miike, Office of Technology Assessment, before the House Committee on Small Business.....

Tests to detect antibodies to the AIDS virus (HIV, for human immunodeficiency virus) consist of two tests performed in sequence. The first test, **EIA** (enzyme immunoassay), detects antibodies to whole and partial virus and measures the total amount of antibodies present in serum, the liquid portion of blood. The second test, the **Western Blot**, is designed to detect antibodies against the major individual proteins that make up the AIDS virus. If an initial EIA test is positive, the test is repeated; if the test is again positive, then a Western blot is performed.

This sequence of tests can provide a very accurate assessment of whether a person's blood contains antibodies to HIV. However, even with a high degree of accuracy, some persons infected with the AIDS virus can be missed (false negative test results), and some can be incorrectly identified (false positive test results) as being infected.

The problem of false positives can take on startling dimensions when applied to low-risk populations, and the false positive problem is a principle reason why concerns have been expressed over proposals for mass testing programs directed at whole classes of people, such as hospitalized patients and the general public.

Even under "best-case" testing, among male military applicants, 3% of positives will be false. By the time we reach the prevalence of U.S. blood donors, 11.1% of positive tests will be false. **The false positive rate is even more dramatic if the accuracy rates of laboratories that participate in open proficiency testing are used.**

The Department of Defense contracts with a single commercial lab, Damon Laboratories, to do all of its testing, with costs at \$4.41 per specimen tested. This price includes both EIA and Western Blot testing. Labs commonly charge a separate price for the EIA and Western Blot. For example, Damon Labs charges individual patients \$47.50 for the EIA and \$121 for the Western Blot. A reasonable estimate of separate charges for negotiated contracts would be \$6 for the EIA, and \$50 for the Western Blot.

Even under ideal testing conditions, antibody-positive specimens will be missed and antibody-negative specimens will be falsely identified as positive. In low-prevalence populations, the percent of positive results that are false increases dramatically and may comprise a major proportion or even most of the positive results. The error rates will be even greater under usual lab testing, so quality assurance programs and proficiency testing of labs engaged in testing for antibodies to the AIDS virus are needed to keep errors to a minimum. Furthermore, because experience with the Western Blot test is still being accumulated, there is lack of agreement on what constitutes a positive Western Blot test.

RESEARCHERS FIND AIDS VIRUS IN URINE--RAISING HOPES FOR SIMPLER DETECTION TEST

The Wall Street Journal reported (on April 11, 1988) that researchers at New York University have detected in urine the presence of the virus that causes AIDS, a finding they said could produce a simpler, faster, and less expensive test for AIDS infection.

In a letter in the April 11 issue of the British science journal Lancet, the researchers said they found evidence of AIDS virus infection in the urine of 79 of 80 patients who also tested positive in blood tests. In an interview, Alvin Friedman-Kien, professor of dermatology and microbiology at New York University Medical Center, said detection of antibodies in urine should allow for the development of a urine-based test for AIDS infection.

Such a test will be less expensive and a more acceptable way to screen huge numbers of people. Antibodies to HIV have been detected in saliva, semen and other human fluids--but never before in urine. NYU is seeking a patent for the technique and is negotiating with several companies to license the process for use in a urine-based test. The researcher decline to name the companies. Companies that make blood-based AIDS antibody tests include: Abbott Laboratories (Abbott Park, IL), DuPont Co. (Wilmington, Del.), and Bristol-Meyers Co. (New York).

Researchers hadn't previously searched urine for the presence of HIV antibodies, Dr. Friedman-Kien said, because blood-borne viruses, such as the one that causes AIDS, usually don't produce antibodies in urine.

In early April, the FDA said it didn't want to approve any home-based AIDS test, saying such tests are more appropriately handled at medical centers. It made the statement in response to companies seeking to provide tests based on blood samples.

GAY RIGHTS GROUPS AND INSURERS BATTLE OVER REQUIRED AIDS TESTS

A recent Wall Street Journal article reported that the John Hancock Mutual Life Insurance Co. has been fighting to deny insurance to those most likely to suffer from AIDS. It has gone to court to kill proposed state regulations, pushed by AIDS-issue groups, that would ban testing for AIDS-virus antibodies as part of health-insurance screening.

Scientists once thought that only 10% or perhaps 20% of all AIDS-virus carriers would contract the disease. But new studies raise the estimate to 30% or more. The government estimates that one million to 1.5 million Americans are infected with the AIDS virus.

So far, the companies have won more battles than they have lost; test bans are currently in effect in only California and the District of Columbia. The Health Insurance Association says AIDS claims cost commercial life and health insurers only \$292 million and amounted to 0.6% of all claims settlements in 1986, the latest year for which figures are available. But over five years through 1991, the group says, health claims alone could total \$10 billion.

Insurers have defeated test-ban bills in several states, and testing is therefore spreading fast. Guidelines adopted by the National Association of Insurance Commissioners rule out considering sexual orientation in underwriting. But 30% of insurers surveyed by the Congressional Office of Technology Assessment say they do so anyway.

Nineteen states, including Florida, already prohibit the practice of limiting AIDS-related coverage to small amounts, in response to pressure from gay rights groups.

SUMMARY OF BLOOD BANKING AND RELATED PROGRAMS

There are about 14 million units of blood donated each year by approximately eight million volunteer blood donors. There are more than 16 million units of blood transfused each year. Persons 65 and older use approximately 43% of all blood units transfused.

There are about 200 free-standing community blood centers in the United States, all of which are affiliated with the American Association of Blood Banks (AABB), the American Red Cross (ARC) or the Council of Community Blood Centers (CCBC). There are also about 600 hospital blood banks and at least 1,500 hospital transfusion services. The more than 2,400 institutional members of the AABB collect about half of the nation's blood supply. The American Red Cross collects the other half. Blood collection establishments must be registered with the Food & Drug Administration.

Beginning in 1982, the AABB has provided information and guidance for those coping with the AIDS crisis, which caused upheaval and change in an industry that had been relatively stable. Through its Transfusion-Transmitted Diseases Committee, AABB developed coalitions with other blood banking and medical organizations. The association's Transfusion Medicine Self-Assessment Program enables clinicians and others to learn the most efficient and effective uses of blood and blood components.

The spread of the AIDS virus, cancer, the increasing amount of heart disease and the growing sophistication with organ transplants requires more research and researchers. The AABB established a research Foundation in 1983, to accomplish that goal, and has launched a campaign to raise \$3 million by 1990.

The AABB also sponsors a variety of programs related to AIDS, such as.

- * Reference Laboratories.....provides for exchange of information and consultation on rare blood group antibodies, typing, crossmatching, component preparation and therapy, blood compatibility testing and research.

- * The Hepatitis and HIV Proficiency Testing Program.....Is conducted with the College of American Pathologists, designed to help labs attain and maintain a high quality of service.

- * The Parentage Testing Program.....provides for accrediting of labs performing parentage testing.

DIAGNOSTIC RELATED GROUPS (DRGs)--THEIR IMPACT ON THE INDUSTRY SINCE 1984

Medical Lab Observer's 1987 DRG survey revealed that.....test volume and productivity are up, budgets are larger, staff cutbacks have eased, attempts to curb inpatient lab utilization have a spotty record, but outpatient testing is thriving. The following section highlights the major findings of MLO's 1987 hospital laboratories survey. Lab directors, managers, and supervisors were polled.

Most of the labs, after four years of the Federal DRG System, are recovering from early rounds of slashed budgets and staff cuts. Test volume and productivity climbed in 1987, budgets are bigger, and staff reductions seem to be abating. Those polled felt that prospective payment has **not** impaired the quality of lab service. In fact, a number say lab quality has actually **improved**.

- * DRG hospitals' average proportion of Medicare cases was 44%, but it can go as high as 60% in some institutions.
- * Because payment for each DRG is a fixed amount regardless of the extent of care, hospitals continue to strive for shorter lengths of stay. The **average stay** was trimmed to 5.4 days in 1987, 6.2 days at larger hospitals. This trend, along with greater reliance on ambulatory care, cut the average hospital occupancy from 66% in 1985 to 62% by 1987.
- * Larger hospitals seem to be in better shape, with 86% expecting to operate in the black, versus 76% for smaller hospitals.
- * **Test activity** keeps increasing at the majority of labs. 70% of surveyed panelists reported that the amount of testing went up during 1987, by an average of 11%. In 1984, the first full year of national prospective payment, annual test volume fell at 44% of hospital labs. Reasons cited for test volume gains were: pressure to attain more rapid diagnosis, a rise in the amount of testing performed in-house, and growth in outpatient testing.

Preadmission testing was up in 1987 at 73% of the hospitals and unchanged at practically all the rest. 58% of labs polled expanded their test menus over the last year, 15% reduced the number of tests offered in-house, and 27% made no change.

- * **Budgets** grew in 1987 at 62% of the labs, by an average of 7%. Budgets were trimmed, however, at 22% of the labs, by an average of 10%.
- * As for **capital expenditures**, 65% of the labs said they did acquire automated instruments. Nearly 60% said that their departments were turned down by hospital administration on a capital expenditure request during the year, though. One laboratorian said: "It seems the administration is hesitant to spend money now in order to make some money down the road."

Machinery makers are trying to make it easier to win approval for purchases. 82% of those surveyed said their labs received more attractive sales offers in 1987.

- * Average **turnaround time** grew longer at 34% of the labs, attributed to a combination of higher workload and insufficient staff.
- * **Quality control** increased at 26% of the surveyed labs, and decreased at 21% of them. Larger instruments are replacing many smaller ones. In hematology, one instrument eliminated manual 200-cell counts for quality control.
- * **Laboratory staffing** was a mixed bag in 1987. 31% of the labs polled increased the number of full-time equivalents, and the same percentage cut back. Among the **smaller** hospitals, 32% hired more lab personnel and 43% stayed the same. At **larger** hospitals, 28% hired more lab personnel, 24% made no change, and a strong 48% cut back. Normal attrition, mentioned by 79% of those polled, accounted for most of the staff reductions.
- * Half of those polled believed that DRGs have had no effect on the **quality of lab service**. One New Jersey lab administrator quotes: "We have been encouraged to analyze tests for what is appropriate and necessary and update our operations. DRGs have made the lab more efficient."
- * 71% of MLO's panelists said that their labs have reduced or eliminated mandatory admission tests, 53% said routine ordering of other tests has ended, and 47% said test order forms were altered.
- * 61% said physicians at their hospitals are monitored for test ordering.

The methods of regulating lab utilization are varied. In 69% of the hospitals monitoring test ordering, committees help do the job. DRG coordinators also play a role, as do: the administration, medical department heads, pathologists, and peer pressure. Hospital information systems track and review test orders, but residents nevertheless order nonessential tests as part of their learning process, in teaching hospitals.

Labs that were **not** successful in trying to cut unnecessary test orders blamed physician resistance to change, combined in some cases with a fear of malpractice actions. Other problems cited were a lack of pathologist involvement and a reluctance to tell physicians about their transgressions.

Urinalysis orders were curbed most often, as well as for complete blood counts, crossmatches, profiles, differentials, cultures, rapid plasma reagin testing, electrolytes, and creatine kinase testing.

- * 69% of surveyed labs have **microcomputers** and/or lab information systems. Of these, 61% use their computers as part of a network interfacing with automated instruments or the hospital's computer.

Only 12% of the hospitals have purchased software designed to track testing for DRG-related trends, and only 8% have developed their own software for that purpose.

Hospital labs have taken other **steps to ease financial pressures**. They include the following.....

- 1) 76% of the labs have sought competitive bids from reference facilities.
- 2) Another popular way to save money, mentioned by 60%, is to secure volume discounts by joining other hospital laboratories in group purchasing.
- 3) Improvement in finances can also be attained by revenue gains, related closely to the topic of **outpatient testing**. Total outpatient testing volume rose at 94% of surveyed labs in 1986, by an average of 15%. 75% of the labs marketed their testing services, with more than 90% marketed to physicians' offices, 66% to nursing homes, 28% to veterinarians, and 27% to ambulatory care centers.

Other "market segments" mentioned by panelists were: industry--targeted for drug testing; the general public (via newspaper ads);

Continued.....

dialysis centers; health maintenance organizations; and small hospital labs. In addition, many hospital administrators are encouraging all department to draw up **marketing plans**. This took place even before DRGs.

- 4) 72% of the labs that market outpatient testing offer courier service, 51% provide phlebotomy at client sites, 33% have installed computer terminals at client sites, 21% have established satellite labs, and 16% have opened area blood drawing stations.
- 5) Price discounts are another important marketing tool, used to counter competition from testing at independent labs.

As for the panelists' opinions regarding their biggest problem related to the DRG system, nearly one-third cited staff cuts which leave behind overworked employees. 27% also mentioned budget cuts. Other problems cited included: reductions in quality and productivity, lower morale, less funding for instruments, loss of revenue, physician failure to comply with test ordering guidelines, and longer turnaround times.

Several respondents also said that the DRG system treats **rural** hospitals unfairly. Rural hospitals get approximately 20% less than an urban hospital, which is a big problem since they compete in the same market and their wages and costs go up just as much.

Another problem cited was that the changes in the Federal reimbursement schedule that are issued usually come out inconsistently. Auditing payments takes a tremendous amount of time. Some hospitals are thinking of retaining DRG consultants, who are paid a percentage of whatever money they save the hospital.

Perhaps the biggest fear is that in watching costs, quality will be compromised. Physicians have to make judgments now that are **financial**, and sometimes in opposition to their **clinical** judgments.

LAB STRATEGIES USED TO CONTROL UTILIZATION SINCE DRGs

Reduced or eliminated mandatory admission tests	71 %
Cut routine ordering for other tests	53
Altered request forms	47
Required medical department approval for certain tests	15
Automatic follow-up testing	12

WHICH OF THE FOLLOWING HELP REGULATE TEST ORDERING BY CLINICIANS ?

Hospital committees	69 %
DRG coordinator	57
Administration	43
Medical department directors	33
Pathologists	33
Peer pressure	28

(61% of clinicians were found to be monitored for test orders per DRG,
39% were not.)

WHICH TESTS HAVE DROPPED IN VOLUME DUE TO MONITORING ?

Urinalysis	28 %	Drug screen	10 %
Complete blood count	26	Glucose	10
Crossmatch	26	Prothrombin time	10
Profiles	21	LD	8
Differential	18		
Cultures	15		
RPR	15		
Electrolytes	13		
CK	13		

OTHER STRATEGIES FOR SAVINGS UNDER DRGs

Sought competitive bids from reference labs	76 %
Joined other hospital labs for group purchasing	60
Shared in-house testing services with other labs	15
Merged operations with another lab	1

LAB MARKETING OF OUTPATIENT TESTING (75% DO, 25% DO NOT)

TO THESE MARKETS.....

Physicians' offices	93 %
Nursing homes	66
Veterinarians	28
Ambulatory care centers	27
Other	21

THE MEDICAL LABORATORIES INDUSTRY

LAB BUDGET RESTRICTION TRENDS - 1987

HAS YOUR LAB TIGHTENED ITS BUDGET OVER THE PAST THREE YEARS ?

If So, What Form Did The Restrictions Take ?

	Independent			— Bed Size —		
	All Labs	Group Practice Labs	All Hospital Labs	Under 200	200-399	400+
Freeze/limitation on filling vacancies	79%	71%	80%	67%	84%	90%
Budget cut	59	55	59	58	53	67
Freeze on capital spending	58	57	58	60	51	57
Freeze/limitation on continuing education	57	43	60	59	60	56
Freeze/limitation on salary increases	47	46	48	54	39	53
Layoffs	38	20	42	64	32	26

SOURCE: Medical Lab Observer - Jan. 1987 Survey

- 44 -

**THE MEDICARE OUTPATIENT CLINICAL LABORATORY
SERVICES PAYMENT SYSTEM -- A PROSPECTIVE
COMPETITIVE BIDDING MODEL**

The Health Care Financing Administration was, in the winter of 1986, in the process of designing a competitive bidding model for the purchase of outpatient clinical laboratory services. Today, more than 4,000 independent clinical labs receive Medicare reimbursement for outpatient tests performed on Medicare beneficiaries. Their size, measured by volume of services, ranges from fewer than 50,000 tests to more than 500,000 tests performed annually. Both hospital labs and physician's offices perform tests for ambulatory Medicare patients.

In 1984, the Laboratory Task Force of the Health Care Financing Administration (HCFA) estimated that Part B **Medicare reimbursement for noninpatient diagnostic lab services in fiscal year 1984 would total approximately \$1.6 billion. About 50% of that amount was expected to be paid to hospitals for outpatient testing. The remaining 50% (\$800 million) was expected to be paid to independent labs and physicians.** The task force also estimated that Part B expenditures for lab services would increase by 15-20% yearly over the next several years, mostly as a result of increased volume of testing rather than higher prices.

As of late 1986, HCFA was in the process of developing a competitive bidding model to be tested as an alternative purchasing and reimbursement method for clinical lab services. HCFA's Office of Research & Demonstrations was planning to test the model in six demonstration sites, beginning January 1987. So far, these demonstrations have **not** taken place, and no bidding model has yet been implemented, due to the moratorium imposed by Congress through the end of 1988.

Medicare's reimbursement of clinical lab services has received much criticism in the past. Two distinct problems were identified. First, labs billed Medicare at a higher rate than they billed physicians for the same service. Second, physician markups of the prices of clinical lab services performed outside their offices were often well in excess of the amount that the physician was charged by the Lab.

In 1980, the **Omnibus Reconciliation Act** was passed, and an attempt was made to rectify these problems. Legislation contained specific provisions for physician billing that prevented reimbursement for markups physicians added when billing for services performed by independent labs.

Prior to June 1984, the amount reimbursed by Medicare to independent labs and those based in physician's offices was based on reasonable charge calculations (i.e. the lowest of customary, prevailing, or actual charges). This method of determining the amount of reimbursement was inherently inflationary.

In section 2303 of the **Deficit Reduction Act of 1984 (DEFRA)**, Congress amended the Social Security Act regarding payments for clinical diagnostic lab tests. The main purpose of this legislation was to contain the growth of Medicare Part B payments for clinical lab tests by altering payment methods and mandating assignment for independent and hospital labs. DEFRA legislation also stipulated that claims for tests may be submitted only by the physician, independent lab, or hospital lab performing the tests.

Payments for clinical lab tests under DEFRA are based on a fee schedule. Fee schedules are established on a carrier-wide basis. Fees are set at 60% of the prevailing charge levles for tests performed by independent labs and by physicians in their offices and at 62% of prevailing charge levels for tests performed by a hospital lab for outpatients.

This reimbursement methodology was to be in effect until June 30, 1987. For tests furnished by physicians in their offices or by independent labs beginning July 1, 1987, the fee schedule was to be established on a nationwide basis. However, with the passage of the Consolidated Omnibus Budget Reconciliation Act in 1986, implementation of the national fee schedule was delayed to January 1, 1988.

THE MEDICAL LABORATORIES INDUSTRY

**MEDICARE-ESTIMATED SUPPLEMENTARY MEDICAL INSUR.
DISBURSEMENTS TO INDEPENDENT LABS
(1975-1986)**

(In Millions)

	<u>AGED</u>	<u>DISABLED + ESRD</u>	<u>TOTAL</u>
1975	\$37	\$2	\$39
1976	45	5	50
1977	55	5	61
1978	66	8	74
1979	85	10	95
1980	102	12	114
1981	138	16	154
1982	160	19	179
1983	199	25	224
1984	252	30	282
1985	504	54	558
1986 EST.	643	76	719

Note: Includes only benefits for services billed directly by provider (i.e. not when billed through physician)

**SOURCE: Health Care Financing Admin., Office of the Actuary,
Office of Medicare Cost Estimates**

THE LABOR SITUATION - STAFF SALARIES, BENEFITS AND PRODUCTIVITY

Medical Laboratory Observer conducted a national survey in January 1987, of 565 members of its Professional Advisory Council. It found that the lab salary and benefits environment had changed substantially from its earlier, 1982 survey. The major finding was that discontent with management compensation eased up slightly, but many supervisors worry about their low-paid staffs.

SALARY TRENDS

Starting annual salaries averaged about \$15,100 for lab technicians in early 1987, \$19,300 for certified technologists, \$23,700 for supervisors, \$27,000 for chief technologists, \$31,700 for lab managers, and \$49,900 for lab directors. Medium-sized (200-399 beds) and larger hospitals continue to pay more than smaller institutions, and the western U.S. still offers the highest average starting salary in most job functions (the South had the lowest salaries). The proportion of management personnel who rated their salaries adequate or better increased from 37% five years ago to 44% by 1987.

Staff from independent and group practice laboratories were moderately more satisfied with their salaries than those from hospital labs. Some hospitals' administrations feel that they "...would rather have excellent productivity and pay for it than have a lot of mediocre people doing mediocre jobs and getting mediocre salaries."

Survey respondents from independent and group practice labs rated their salaries higher more often than hospital lab staffers did--22% versus 14%.

The average lab salary increase over the past year (1986) was 5.2%, with raises slightly higher at independent and group practice labs and at larger hospital labs. In 1982, salaries rose a strong 9.1% on average, when inflation was much higher in the overall U.S. economy. Salaries are adjusted yearly at 90% of the respondents' labs. But, 10% of these staffers hadn't had a raise in more than a year, and another 7% hadn't had one in two or more years. Salary cuts and freezes have taken place.

At some labs in the Midwest, all wages were frozen for two years, and employees took a 10% reduction in hours. Other labs reported that merit raises cease once an employee reaches the maximum salary in a grade, but cost of living increases continue.

Fully 45% of surveyed labs offer merit raises, 37% offer cost of living adjustments, and 16% offer bonuses. 35% of the **Independent labs** pay bonuses, compared to only 11% of hospital labs.

TURNOVER

Many younger staffers have totally changed fields, moving on to sales, nursing, administration, infection control, etc. Many lab directors feel that the field is female-dominated, and salaries have been kept low because of the rationale that "women don't need as much money as men."

In 1981, many lab managers predicted a talent drain if pay levels didn't start improving significantly over the next few years. Salaries **did** improve, but lab administrators and supervisors generally don't think the gains were big enough. **Widespread dissatisfaction is reported, causing job hopping and an exodus from the profession.** They also see fewer college students choosing medical technology careers. Turnover would have been much higher if DRGs had not limited clinical lab job opportunities. The consequence is that morale is slipping in many labs.

In **hospital** labs, the employment drain is regarded as diagnostic service directors' biggest problem. One director in Massachusetts comments: "People are leaving hospitals now because we can't pay them enough. It's harder to attract medical technologists when they can get more money going into private clinics, physicians' offices, and reference laboratories, without the burden of nights and weekends.

MLO's **DRG (Diagnostic Related Group) 1987 survey** revealed that overtime increased at 27% of the labs and decreased at 18%. Productivity over the past year was said to have risen at 72% of the labs surveyed, with increases averaging 10.8%, and declines 7.7%.

Lab managers worry that the greater the pressure on a reduced staff to provide a volume of work, the greater the chance for error. Directors report that all the "free time" is gone for things like testing new kits. If someone is out sick, there is frequently a lot more juggling. "Staffing has decreased, turnaround time has increased. Both have had an adverse impact on quality."

EMPLOYEE BENEFITS

As for benefits, paid vacations, sick leave, and medical insurance are universal, and life insurance and a pension plan are offered by 90% of labs. Most also provide maternity leave, paid expenses for seminars and

workshops, paid tuition, and a dental plan. Now, 71% of labs have dental insurance, versus 50% five years ago. Most benefits receive high marks from lab employees.

BUDGET CUTBACKS, MORALE & PRODUCTIVITY

Fully 82% of labs responding to MLO's survey said that their labs underwent budget reductions or freezes over the last three years. The most widespread restriction (faced by 79% of the affected labs) was a freeze or limitation on filling job vacancies. 59% of the labs experienced budget cuts, 58% had a freeze on capital spending, 57% had to limit continuing education, 47% had to limit salary increases, and 38% had layoffs. A total of 69% of the respondents attributed these restrictions to DRGs.

Budget tightening has affected morale at 86% of these labs surveyed.. Efficiency has been affected at 55% of the labs, and turnover has been affected at 43% of labs. "Odd shift patterns, uncertainty about being able to work a full 40-hr. week, and salary freezes have created morale problems." **Many lab directors report that employees have little enthusiasm or sense of worth. People are constantly job hunting, apathy is increasing, and so efficiency is, not surprisingly, less than ideal.** Some labs are operating with skeleton crews--making it virtually impossible to provide quality service. **"Hurrying due to understaffing has caused careful technologists to make errors they never made before."**

SALARY FORECASTS

Fully 90% of survey repondents detected salary dissatisfaction among their co-workers, with 63% "moderately dissatisfied". By region, the South has the highest proportion of "very dissatisfied" ratings.....34%. MLO reports that these ratings are practically identical to the 1982 survey, which indicates that the situation has **not** gotten better over the last five years. **Most lab directors surveyed forecast that more lab personnel will leave the profession, and it will be difficult to attract replacements.** Several labs located in Texas reported that, due to DRG-induced layoffs, there were more applicants than job opportunities.

87% of the laboratorians surveyed forecast tha' salaries will not improve appreciably over the next five years. That is a worse scenario than in 1982, when 64% were negative about future salary prospects. Hospital

budgetary problems are the main reason salaries will not improve. However, some feel that the industry is in the middle of a recurring 25-year cycle of glutting the field, then weeding out employees to create a shortage. They predict such a shortage again, as early as 1990.

THE MEDICAL LABORATORIES INDUSTRY

GEOGRAPHIC SALARY COMPARISONS, SALARY INCREASES IN LABS (1987)

HOW DO YOU (Supervisors) COMPARE IN SALARY WITH OTHER LABORATORIANS HOLDING A SIMILAR JOB IN YOUR GEOGRAPHIC AREA ?

	Independent			----- Bed Size -----		
	All Labs	Group Practice Labs	All Hospital Labs	Under 200	200-399	400+
My Salary Is:	----- PERCENT -----					
Higher	16	22	14	11	13	16
About Same	40	41	40	29	43	43
Lower	30	28	31	46	24	28
Don't Know	14	9	15	14	20	13

HOW BIG WAS YOUR LAST RAISE ?

All Labs	5.2 %
Independent Group Practice Labs	5.7
<u>All Hosp. Labs</u>	<u>5.1</u>
under 200 bed	4.7
200-399	4.9
400+	5.6

BEYOND REGULAR SALARY INCREASES, WHICH OF THE FOLLOWING DOES YOUR LAB PROVIDE ?

Merit Raises	45%
Cost of Living Adjustments	37
Bonuses	16

SOURCE: Medical Lab Observer-Jan. 1987 Survey

THE MEDICAL LABORATORIES INDUSTRY

1987 STARTING SALARIES IN LABS. BY TYPE & SIZE LAB

				----- Bed Size -----		
	All Labs	Independent Group Practice Labs	All Hospital Labs	Under 200	200-399	400+
Technician	\$ 15, 140	\$ 14, 515	\$ 15, 311	\$ 14, 318	\$ 15, 931	\$ 15, 493
Technologist	19, 344	18, 828	19, 499	18, 811	20, 101	19, 589
Supervisor	23, 667	23, 833	23, 663	21, 241	23, 798	25, 487
Chief Technol.	26, 972	25, 785	27, 389	24, 956	27, 674	27, 499
Lab Manager	31, 722	30, 596	31, 946	27, 949	32, 491	34, 432
Lab Director	49, 923	44, 383	51, 529	45, 400	53, 160	52, 991

----- BY REGION -----

	<u>EAST</u>	<u>SOUTH</u>	<u>MIDWEST</u>	<u>WEST</u>
Technician	15, 802	14, 340	14, 950	15, 815
Technologist	18, 693	18, 273	18, 977	22, 353
Supervisor	24, 596	22, 037	22, 933	25, 562
Chief Technol.	26, 406	24, 773	27, 083	30, 050
Lab Manager	32, 533	29, 238	30, 922	35, 221
Lab Director	53, 500	44, 732	48, 809	52, 718

SOURCE: Medical Laboratory Observer, Annual Survey-Jan. 1987

THE MEDICAL LABORATORIES INDUSTRY

EMPLOYEE BENEFITS OFFERED TO EMPLOYEES BY LABS

	<u>Percentage Of Labs Offering</u>
Paid vacation	100%
Paid sick leave	99
Medical insurance	98
Life insurance	91
Pension plan	89
Maternity leave	84
Paid seminar/workshop expenses	84
Paid tuition	72
Dental plan	71
Paid parking	39
Paid uniforms	27
Paid professional member. dues	26
Child day care	13
Laundry allowance	12
Meal allowance	10

SOURCE: Medical Lab Observer - Jan. 1987 Survey

Industry analysts such as the stock brokerage house Smith Barney estimate the total U.S. clinical laboratory testing market to be worth from \$16 to \$20 billion annually, with the test market broken down by the following types of labs:

Hospital labs	50 % of revenues
Physician in-office labs	25
Independent commercial labs	25

The U.S. Census Bureau, in its "Service Annual Survey" series, reports that **Independent** medical labs had revenues of **\$4.378 billion during 1986**. Growth in receipts for these labs since 1978 has been strong, averaging 13.2% increases per year, and never lower than 6.7%. The 6.7% increase was posted during the first year of implementation of the new Medicare diagnostic related group (DRG) payment system--in 1984. Based on this eight year trend, and the current situation of strong demand for AIDS and drug abuse testing, **Marketdata estimates that independent labs' receipts will have risen 12.5% in 1987 and 1988, to \$4.925 billion in 1987 and \$5.54 billion in the current year. Through 1993, we forecast a return to historical growth rates of 13.2% annually, to \$9.916 billion by 1993.**

In the short term, it is likely that the independent labs and physician in-office labs will capture a slightly higher share of the total test market than in-hospital labs, which are affected more by budget cuts and cost control measures that keep test prices down. Consequently, Marketdata estimates that the test market for 1988 will be divided as follows:

Hospital labs	46 % of revenues
Independent labs	28
Physician office labs	26

Six large lab company chains capture a major share of the test market. Marketdata estimates that these six combined, with revenues of \$1.3 billion, accounted for at least 30% of the independent lab test market in 1986. This estimate is based on company sales (as reported in annual reports and financial reports), relative to Department of Commerce figures from the Service Annual Survey.

Following are these six firms' sales for 1986.....

SmithKline Bio-Science Labs	\$372 million
Roche Biomedical (Hoffmann LaRoche)	255
MetPath (Corning Glass Works)	215
National Health Labs (Revlon Group)	189
International Clinical Labs (ICL)	168
Damon Corp.	<u>98</u>
Total:	\$1,297 mill.

Analysts estimate that these companies account for 52% of the total \$2.4 billion national "reference lab" market. An update to these rankings should include the April 1988 acquisition of ICL by SmithKline.

An estimated 50-100,000 physicians now do their own testing, and the number is growing rapidly as they purchase relatively inexpensive "black Box" analyzers in the \$5,000 range.

There are over 11,000 federally registered clinical labs, 4,368 Medicare-approved independent labs, and 6,658 Medicare-approved hospitals in the United States.

TEST MARKET SEGMENTS

Blood Cholesterol testing represents a \$1.5 billion market currently. A government panel recently suggested that all adults have their cholesterol levels tested, an action which could boost spending on such tests to \$3 billion per year (according to Health Business). Approximately 100 million blood cholesterol tests were performed in the U.S. during 1987. It is among the most common lab procedures.

However, there are concerns about test accuracy, related to the methods used to determine cholesterol levels and the fact that there are more than 30 different analytical instruments on the market today, each using somewhat different chemical processes. In addition, machines frequently are not calibrated properly by technicians. There is a dire need for manufacturers to develop a standardized protocol. (see later section: The Cry For Federal Regulation, for more details). The major equipment

suppliers to this test market include: Abbott Labs, Beckman Instruments, and Eastman Kodak.

Pap Smear tests have become another of the most common lab tests, as an early predictor of cervical cancer in women. However, it is also the test which has come under the most scrutiny of late, for error rates estimated between 20% and 40%. The media, and now several Congressional committees, have begun investigating dubious lab quality control and work practices, as well as individual companies doing the tests. Congressman Wyden has introduced a new bill, and eight states now have implemented legislation.

The best estimate of the total U.S. volume of Pap smear tests performed annually, from a consensus of leading experts at the Center For Disease Control and National Cancer Institute, is **60 million tests per year**. Virtually all major clinical labs report increasing activity in Pap smears, although the percentage growth rate is not known. At 60 million tests annually, typically at a cost of \$12 each (charged by the lab), this probably represents a **\$720 million annual market**. If one considers that doctors often mark up the price of Pap tests as high as \$35 to the patient, the market ranges from \$720 million to \$2.1 billion at the high end.

The biggest lab in the nation for Pap smears is Cancer Screening Services of North Hollywood, CA. They performed nearly one million cases during 1986. Another major firm in this area is Cancer Screening Labs of San Antonio, TX, which performs about 500,000 tests per year. The Planned Parenthood Federation of America, through its affiliates, performed 1.4 million Pap tests during 1986. **At a typical cost to the patient of about \$35, these three organizations alone, with 2.9 million tests, represents about \$101 million in test activity yearly.**

(Refer to the later section entitled: The Cry For Federal Regulation, for more details about Pap tests.)

As Pap smear test volume is rising, the number of ~~qualified~~ screeners (cytotechs or cytologists) is falling. To cope with this labor squeeze, labs are permitting workers to do extra tests on a piecework basis (50 cents per slide is the typical pay scale), a practice that encourages overwork and increases chance of error. Industry professional societies recommend that cytotechs examine a maximum of 12,000 slides per year, but this limit is regularly ignored, with volumes approaching 35,000 per year per worker in some cases. The Health Care Financing Administration is

expected to unveil comprehensive regulatory reforms soon, to address the quality issues in Pap tests and other lab work.

WORKPLACE EMPLOYEE DRUG TESTING

Employee drug testing is estimated to become a \$160 million market by 1990. Approximately 713,000 work place drug tests were administered during 1985, and that number no doubt has risen substantially in three years. Standard & Poors divided the drug testing market as follows:

Commercial labs	30% of the market
Military screening	27
Hospital labs	16
On-site testing	14
International business	9

Federal agency test activity is higher right now than in corporate America, due to the nature of many jobs, which involve the public safety (transportation fields-FAA), and the military. As many as 20 federal agencies are to start testing soon, covering an estimated 30,000 employees in 1988. The agencies that do perform testing now include: the Transportation Dept., the FAA, FBI, Drug Enforcement Administration, Customs Service, Army, Navy, and Air Force.

On the corporate side of the picture, a 1987 American Management Association study found that of 1,000 companies surveyed, 34% had drug testing programs, versus 21% during 1986. But, many employees are challenging drug tests as an invasion of privacy rights, and firms will tread carefully on this new ground to avoid potential lawsuits. Pharmchem Labs (Menlo Park, CA) is a major player in this market, and conducted 9,000 tests per month in 1985 (15% of their total business). The firm expects that such tests accounted for a larger share (25%) of their business by 1987. **It is estimated that 30% of the Fortune 500 companies now require pre-employment or workplace drug tests.**

Basically, there are three types of drug tests, based on immunoassay and TLC (thin layer chromatography) methods: 1) urine drug tests, 2) blood tests, and 3) hair analysis. Urine tests are considered the most accurate, and are the most prevalent currently.

AIDS TESTING

AIDS screening is not currently a high volume test, but is doubling every six months, according to some analysts. One must be careful with such an estimate, however, since this may be true of the smaller volume market segment that includes hospitals, reference labs, and state health departments, but **not** of the very large volume testers such as the American Red Cross.

The Center For Disease Control (CDC) in Atlanta, GA reports that probably **70% of all AIDS testing is performed by public health agencies such as blood banks** (anonymous or "alternative" test sites). Over 15 million tests are performed annually, by the **American Red Cross and the Community Council of Blood Centers**. The American Association of Blood Banks (Arlington, VA) reports that 14 million units of blood are tested per year for the AIDS virus, a number that has remained fairly stable since testing was begun in early 1985. Typically, the test costs \$2, which is factored into the total bill to the hospital. **Consequently, this segment constitutes a \$28 million annual potential.**

The second largest market segment for AIDS testing is the military, which may perform several million tests per year. Damon Corp. is the main provider of AIDS tests to the military, via its "negotiated contract" agreement. Damon Corp. typically charges individual patients about \$48 for the EIA AIDS test, and \$121 for the Western Blot test. Higher volume, negotiated contracts (for the Government, military, etc.) cost \$6 for EIA and \$50 for the Western Blot.

The Elisa or EIA test is the first AIDS screening test performed. If a patient tests positive on this one, a "Western Blot" is performed. Prices may vary from no charge at all (tests by public health agencies), to a range of \$25-75.

These HIV blood tests are performed by an increasing number of **counseling centers and test sites**. As of 1987, there were approximately 1,100 such test sites in the country, up from 917 in 1986 and 874 in 1985.

The best estimates of the **number of AIDS tests** currently performed by hospitals, reference labs, and state health departments (excluding the military and tests done by blood banks) are as follows:

1988	800,000 (Projected)
1987	550,000
1986	180,000
1985	79,000

A good indicator of the extent of AIDS testing is the number of **test kits** licensed by the FDA and sold to agencies such as the CDC. These kits typically sell for about \$1.00 each, and are used for testing of rubella, hepatitis, and other diseases, as well as AIDS.

The FDA reports that eight major manufacturers are licensed by them to sell kits. The companies that are licensed are: Abbott Laboratories, Electronucleonics, Organon Teknika, Cellular Products, E.I. DuPont, Genetic Systems, Ortho Diagnostics, and Biotech Research Labs. The FDA also stated that there are many other unlicensed companies performing AIDS tests as well. **The biggest players in the AIDS testing market are state health departments**, also not regulated by the FDA. They may be involved in pre-marital screening when people apply for marriage licenses.

Within this **non-military, non-blood bank test market**, if one assumes that there is a 75/25 mix of negotiated contract versus individual patient AIDS tests performed, at average costs of \$56 and \$169 respectively (see prices charged by Damon Corp. - above) the AIDS testing market in 1988 would be worth about \$67 million (600,000 tests X \$56 plus 200,000 tests X \$169 = \$33.6 million plus \$33.8 million).

Therefore, combining the blood bank and much smaller hospital/state health department market segments, **the AIDS testing potential per year is worth at least \$95 million**. Military tests would have to be added to this figure, probably worth another \$10 million. It is difficult to pin down the exact size of the market because there is no hard data on the number of EIA vs. Western Blot tests performed. The latter is not performed unless a positive result is obtained on the first (EIA) test.

HEALTH & FITNESS TESTS

An estimated 35% of all "health tests" in the U.S. are performed by independent labs, and it is a fast-growing area. This involves stress tests and hair analyses.

THE MEDICAL LABORATORIES INDUSTRY

ESTIMATED ANNUAL RECEIPTS AND YEARLY PERCENT CHANGES
MEDICAL LABS

	<u>RECEIPTS</u> (\$ Millions)	<u>PERCENT CHANGE</u>	
1978	\$ 1,629		
1979	1,934	18.7	
1980	2,160	11.7	
1981	2,408	11.5	
1982	2,820	17.1	
1983	3,221	14.2	
1984	3,437	6.7	
1985	3,844	11.8	
1986	4,378	13.9	
<u>ESTIMATE</u>			
1987	4,925	12.5	(average annual rate)
1988	5,540	12.5	
<u>FORECAST</u>			
1993	9,196	13.2 *	(average annual rate)

* Average annual rate, assuming an economic recessions in 1989.

SOURCE: U.S. Census Bureau, Current Business Reports,
Service Annual Surveys

STRUCTURE OF THE INDEPENDENT CLINICAL LAB INDUSTRY

As of the last U.S. Census of Service Industries, conducted during 1982, there were a total of 12,195 medical and dental laboratories combined, operating in the country. The national Yellow Pages directories report that in 1987 there were 6,050 **medical** labs alone. The states with the greatest number of labs are:

California	1,124
New York	436
Texas	376
Florida	349
Ohio	302
Illinois	252
Massachusetts	220

Over the next 10-20 years, due to a continuation of rapid population growth (spurred in large part by the aging U.S. population and retirees) occurring in that state, **Florida** will probably add the greatest number of clinical labs.

Separate data for medical and dental labs are not available from the Department of Commerce. Rather, the information is combined. It is true that their businesses are different, but these two types of labs no doubt do share many similar operating characteristics, and an analysis of this combined data is useful.

Of the 12,195 medical & dental labs in operation in 1982, more than 60% were classified as **corporations**, while 28% were **individual proprietorships** and 10.7% were **partnerships**.

Payroll costs averaged 39.7% of each sales dollar, with corporations having significantly higher labor costs than either proprietorships or partnerships (41.7% vs. about 29%).

Medical & dental labs employed 8.5 workers, on average, in 1982. Corporations employed an average of 11.7 people, while proprietorships employed only 2.9 and partnerships employed 5.5 workers.

Fully 86% of all medical & dental labs in 1982 were **"single unit"** labs, compared to about **14% "multi unit"** types. About 55% of total receipts were accounted for by single unit firms, while about 43% of receipts were captured by multi unit labs. Therefore, although multi unit labs accounted for the minority, in total number, they wield a lot of clout in capturing sales dollars.

Labor costs tend to be highest for those operations with 2-4 labs. Those operations with 10 or more facilities had the lowest payroll costs relative to sales--about 36%. Those operations with 10 or more facilities captured nearly 25% of total receipts.

The most prevalent **size** lab is one that did **\$100,000-250,000** in business per year in 1982 (3,399 labs), followed by labs that took in \$50-100,000 annually (2,746). There were 690 that did \$1 million or more. These sales volumes don't sound high, but one must remember that these are sales per **lab**--not per total **company**. And, one would have to adjust these 1982 numbers to the growth and inflation that has taken place in six years to 1988. Labs of the \$5 million sales size accounted for nearly 20% of total receipts, and those in the \$1-2.5 million size accounted for 18%. Payroll costs were highest (43.8% of each sales dollar) for the smallest labs (under \$10,000), and lowest for those in the \$25-50,000 class (33.8%).

By sales size of the company or firm, there were only three firms that took in \$100 million or more, and another 22 that took in \$10-100 million. 40 firms had sales of \$5-10 million.

By employment size of the firm, over 60% of all firms employed less than 5 workers in 1982. An additional 18% employed 5-9 workers, and 9% employed 10-19 workers.

FINANCIAL HEALTH OF MEDICAL LABS

According to the Robert Morris annual financial statement studies, a well-known directory that analyzes "composite" income statements, balance sheets, and key financial ratios for a wide range of industries, **operating expenses** remained stable or declined slightly in the five years from 1983 to March of 1987--a good sign. Operating expenses of medical labs represented 89.3% of each sales dollar in 1987, compared to 91.6% back in 1983. Therefore, **operating profits** rose from 8.4% to 10.7% of sales.

However, **"all other expenses"** rose from 1.5% to 4% of sales, a trend which contributed to labs' **pre-tax profits** being eroded slightly to 6.7% of sales. **Debt loads** increased significantly during 1987, representing a 5-year high of 2.0% of net worth. Perhaps most noticeable is the fact that in the past two years, owners of medical labs have taken a lot more money out of the business for themselves. **"Officers' compensation relative**

to sales" stood at 16.7% in 1987, compared to 9.8% in 1985. This is a big jump.

As for balance sheet measures, a typical medical lab carries 27-30% of its assets in the form of **trade receivables**, 4.2% in **inventory**, and about 13.5% in **cash**. About 39% of total assets are in the form of **net fixed assets**. **Long-term debt** represented 24.6% of total liabilities for medical labs in 1987, a five-year peak. **Net worth**, conversely, declined from 43.5% in 1985 to 34.0% by 1987. **Trade payables** are about 9% of total liabilities, and **short-term notes payable** represent about 6.5%.

All in all, medical labs are fairly profitable ventures, compared to other businesses, but they require substantial fixed asset investment (automated analyzers/equipment). Receivables management is important, since they represent nearly one-third of total assets. Cost control, especially factors not related directly to operating expenses, is important as well, since it significantly affects pre-tax profits. Owners may have to be careful about taking too much money out of the business, if by doing so they neglect adequate pay raises for their technical staff, cut back on quality control procedures, or don't keep up with the latest testing technologies and instruments. This will enrich them in the *short term*, but will undermine their ability to compete and grow in the future.

THE MEDICAL LABORATORIES INDUSTRY

NUMBER OF MEDICAL LABS, BY STATE - 1987

State	Number Of Labs	State	Number Of Labs
ALABAMA	59	MONTANA	12
ALASKA	11	NEBRASKA	18
ARIZONA	135	NEVADA	22
ARKANSAS	34	NEW HAMPSHIRE	20
CALIFORNIA	1124	NEW JERSEY	186
COLORADO	97	NEW MEXICO	65
CONNECTICUT	189	NEW YORK	436
DELAWARE	46	NO. CAROLINA	69
DIST. OF COL.	17	NORTH DAKOTA	8
FLORIDA	349	OHIO	302
GEORGIA	114	OKLAHOMA	77
HAWAII	50	OREGON	66
IDAHO	21	PENNSYLVANIA	199
ILLINOIS	252	RHODE ISLAND	77
INDIANA	145	SO. CAROLINA	31
IOWA	32	SOUTH DAKOTA	8
KANSAS	39	TENNESSEE	84
KENTUCKY	73	TEXAS	376
LOUISIANA	99	UTAH	41
MAINE	11	VERMONT	6
MARYLAND	185	VIRGINIA	99
MASSACHUSETTS	220	WASHINGTON	110
MICHIGAN	199	W. VIRGINIA	32
MINNESOTA	26	WISCONSIN	39
MISSISSIPPI	26	WYOMING	11
MISSOURI	113		
		U.S. TOTAL:	6,050

SOURCE: American Business Lists, Yellow Pages Directories

THE MEDICAL LABORATORIES INDUSTRY

NUMBER OF LABS BY SPECIALTY PERFORMED

<u>SPECIALTY AREA:</u>	<u>NUMBER OF LABS PERFORMING</u>
Chemistry	2, 635
Chemistry - Routine	2, 809
Chemistry - Clinical Microscopy	2, 802
Chemistry - Other	2, 970
Hematology	2, 836
Histocompatibility	141
Immunohematology	280
Immunohematology - Blood Group	1, 414
Immunohematology - RH Titers	975
Immunohematology - Cross Match	288
Immunohematology - Other	943
Microbiology	313
Microbiology - Bacteriology	2, 109
Microbiology - Mycology	976
Microbiology - Parasitology	1, 464
Microbiology - Virology	411
Microbiology - Other	358
Pathology	942
Pathology - Tissue	1, 132
Pathology - Oral	975
Pathology - Diagnostic Cytology	1, 391
Physiological Testing	615
Physiological Testing - EKG Serv.	615
Radioassay	183
Serology	2, 107
Serology - Syphilis	2, 107
Serology - Other	2, 945
Total No. of Labs:	4, 080

SOURCE: RADARS, March 1986

THE MEDICAL LABORATORIES INDUSTRY

ECONOMIC STATISTICS

MEDICAL & DENTAL LABS, BY LEGAL FORM OF ORGANIZATION

	<u>1982</u>			
	<u>TOTAL NO. OF LABS</u>	<u>RECEIPTS</u> (\$ Mill.)	<u>PAYROLL AS % RECEIPTS</u>	<u>NO. OF EMPLOYEES</u>
ALL TYPES	<u>12, 195</u>	<u>\$ 4, 082.6</u>	<u>39.7</u>	<u>103, 711</u>
Corporations	7362	3, 383.9	41.7	85, 945
Individual Prop.	3468	356.6	29.1	9921
Partnerships	1306	317.9	28.8	7198
Other	59	24.2	46.6	647

SOURCE: U.S. Census of Service Industries, Dept. of Commerce

THE MEDICAL LABORATORIES INDUSTRY

ECONOMIC STATISTICS
LABS, BY SINGLE & MULTI-UNIT FIRMS

1982

	<u>NO. OF FIRMS</u>	<u>NO. OF LABS</u>	<u>ANNUAL RECEIPTS (\$ Mill.)</u>	<u>PAYROLL AS % RECEIPTS</u>	<u>NO. OF EMPLOYEES</u>
<u>ALL FIRMS</u>	<u>10, 999</u>	<u>12, 195</u>	<u>\$ 4, 082.6</u>	<u>39.7</u>	<u>103, 711</u>
SINGLE UNITS	10, 504	10, 504	2, 253.1	40.9	60, 825
<u>MULTI UNITS</u>	495	1691	1, 737.2	38.3	39, 795
1 Facility	172	172	150.7	39.7	3779
2 Facilities	169	338	184.0	45.6	4604
3 or 4 "	82	274	157.4	42.5	3860
5 - 9 "	48	289	235.2	38.1	5357
10 or more "	24	618	1, 009.8	36.2	22, 195

SOURCE: U.S. Census of Service Industries, Dept. of Commerce

THE MEDICAL LABORATORIES INDUSTRY

ECONOMIC STATISTICS
MEDICAL & DENTAL LABS, BY RECEIPTS SIZE OF LAB

SALES SIZE OF THE LAB	NO. OF LABS	1982		
		RECEIPTS (\$ Mill.)	% OF TOTAL RECEIPTS	ANNUAL PAYROLL AS % RECEIPTS
TOTAL:	12, 195	\$ 4, 082.6	100. 0	39.7
Facilities Open Entire Year	11, 637	3, 854. 0	94.4	39.8
\$5 Million	74	791.2	19.4	38.2
2.5 - 5 Million	132	458.3	11.2	38.2
1 - 2.5 "	484	741. 0	18.1	41.2
500K - 1 million	785	554.5	13.6	42.6
250-500K	1443	498.6	12.2	42.7
100-250K	3399	535.2	13.1	38.7
50-100K	2746	202.9	5. 0	34. 0
25-50K	1566	57.6	1.4	33.8
10-25K	794	13.6	0.3	38.4
Under \$10,000	214	1.2	—	43.8
Facilities Not Open Entire Year	558	228.6	5.6	37.7

SOURCE: U.S. Census of Service Industries, Dept. of Commerce

THE MEDICAL LABORATORIES INDUSTRY
ECONOMIC STATISTICS
MEDICAL & DENTAL LABS, BY ANNUAL RECEIPTS SIZE OF FIRMS

<u>SIZE OF FIRM</u>	<u>1982</u>				
	<u>NO. OF FIRMS</u>	<u>NO. OF LABS</u>	<u>ANNUAL RECEIPTS</u> (\$ Mill.)	<u>ANNUAL PAYROLL</u> (\$ Mill.)	<u>NO. OF EMPLOYEES</u>
ALL FIRMS	10, 999	12, 195	\$ 4, 082.6	\$ 1, 619.5	103, 711
\$100 Mill. or more	3	210	487.2	169.0	10, 437
50-100 mill.	22	358	644.7	242.3	13, 975
25-50 "					
10-25 "					
5-10 "	40	124	256.0	93.6	4975
2.5-5 "	103	250	349.6	145.8	8371
1-2.5 "	388	578	540.5	255.6	14, 136
500K-1 mill.	638	758	448.1	199.9	12, 031
250-500K	1267	1340	434.8	187.6	12, 383
100-250K	3100	3127	488.0	189.6	14, 194
less than 100K	4949	4957	255.3	86.1	8, 808
Firms Operating Entire year	10, 510	11, 702	3, 944.2	1, 569.5	99, 310
Firms Not Oper. Entire year	489	493	138.4	50.0	4401

SOURCE: Census of Service Industries, Dept. of Commerce

THE MEDICAL LABORATORIES INDUSTRY

ECONOMIC STATISTICS
MEDICAL & DENTAL LABS, BY EMPLOYMENT SIZE OF FIRMS

SIZE OF FIRM	1982			
	NO. OF FIRMS	NO. OF LABS	ANNUAL RECEIPTS (Millions)	NO. OF EMPLOYEES
ALL FIRMS	10,999	12,195	\$ 4,082.6	103,711
Less Than 5 employees	6667	6685	549.8	13,228
5 - 9	2018	2064	465.1	13,083
10 - 19	1012	1113	484.8	13,173
20 - 49	576	756	620.5	16,908
50 - 99	149	323	378.9	10,129
100 - 249	64	199	323.4	8546
250 - 499	12	100	200.7	4240
500 - 999	4	72	90.2	2406
1000+	8	390	830.8	17,597
Firms Not Operating Entire Year	489	493	138.4	4401

SOURCE: U.S. Census of Service Industries, Dept. of Commerce

THE MEDICAL LABORATORIES INDSTRY

AVERAGE RECEIPTS & AVERAGE EMPLOYMENT PER LAB AND LAI BY SALES SIZE OF LAB OR FIRM: 1982

<u>SALES SIZE OF LAB</u>	<u>AVG. RECEIPTS PER LAB (\$ Thousands)</u>
All Labs	\$334.8
Facilities Open Entire Year	331.2
\$5 million	10,691.9
2.5-5 "	3,472.0
1-2.5 "	1,531.0
500K-1 mill.	706.4
250-500K	345.5
100-250K	157.5
50-100K	73.9
25-50K	36.8
10-25k	17.2
Under \$10,000	5.6
Facil. not open entire year	409.7

<u>By Sales Size:</u>	<u>AVG. NO. OF EMPLOYEES PER LAB FIRM</u>
All Firms	8.5
\$100 mill. or more	49.7
50-100 mill.	
25-50 "	
10-25 "	39.0
5-10 "	40.1
2.5-5 "	33.5
1-2.5 "	24.5
500K-1 mill.	15.9
250-500K "	9.2
100-250K "	4.5
Less than 100K	1.8
Firms operating entire yr.	8.5
Firms not oper. entire year	8.9

SOURCE: Calculated by Marketdata from Census Data

THE MEDICAL LABORATORIES INDUSTRY

COMPOSITE FINANCIAL STATEMENTS—MEDICAL LABS
ALL ASSET SIZES—GROUP AS A WHOLE
HISTORICAL DATA - 9 MONTHS (JUNE 30—NEXT MARCH 31)

	1983	1984	1985	1986	1987
NO. OF STATEMENTS	62	71	95	92	138
BALANCE SHEET					
ASSETS	% of Total				
Cash & equivalents	13.5	13.4	13.6	17.6	12.7
Net trade receivables	27.3	24.7	28.0	27.1	30.1
Inventory	7.0	4.2	3.3	2.3	4.2
All other current	4.0	2.7	3.1	2.7	2.1
Total current	51.8	44.9	48.0	49.7	49.1
Net fixed assets	38.0	38.8	39.2	38.5	39.1
Net intangibles	1.4	2.4	2.9	1.4	2.2
All other non-current	8.8	13.9	9.9	10.4	9.6
LIABILITIES					
Short term notes payable	6.9	6.7	5.1	8.2	6.3
Curr. Mat.-LT debt	6.3	5.2	7.1	6.4	9.4
Trade payables	9.8	9.0	9.0	8.3	8.5
Income taxes payable	—	—	0.9	2.5	1.9
All other current	11.7	12.9	10.8	9.6	12.1
Total current	34.7	33.9	32.9	35.0	38.1
Long term debt	20.4	19.9	21.0	20.6	24.6
Deferred taxes	—	—	1.5	1.7	1.3
All other non-current	2.4	2.7	2.1	3.1	2.0
Net worth	42.5	43.5	42.5	39.6	34.0
INCOME STATEMENT					
Net sales	100.0	100.0	100.0	100.0	100.0
Operating Expenses	91.6	88.1	90.0	89.4	89.3
Operating Profit	8.4	11.9	10.0	10.6	10.7
All Other Expenses (net)	1.5	2.5	3.9	3.1	4.0
Profit Before Taxes	7.0	9.4	6.1	7.5	6.7
RATIOS					
Current	1.5	1.5	1.4	1.4	1.4
Debt/worth	1.4	1.2	1.5	1.2	2.0
% Prof.bef.tax/tot.assets	9.7	10.8	8.1	11.8	10.6
% Officers' comp./Sales	8.8	11.6	9.8	15.7	16.7

SOURCE: Robert Morris Associates, Annual Financial Statements

A bill expanding the scope of the Clinical Laboratories Improvement Act of 1967 has been introduced by Rep. Ron Wyden (Democrat-Oregon). Under this bill, named the **Medical Testing Improvements Act of 1988**, both interstate and intrastate labs would have to be licensed and inspected every year, and participate in quarterly proficiency testing to assess their performance. Hospital, inter- and intrastate labs would be affected as of Jan. 1, 1990, but physician office labs (POLs) would not be affected until 1992. **The federal government spends \$1.6 billion per year on lab work**, according to the testimony of various senators.

Under present Medicare policy, doctors providing lab tests for their own patients are exempt from Medicare standards applied to other labs. In 1987, however, Congress decreed that high-volume POLs (those performing more than 5,000 lab tests annually) will be subject to Medicare independent lab standards as of Jan. 1, 1990. These standards prescribe training and experience requirements for lab personnel (director, supervisor, technologist, technicians) along with proficiency testing, quality control, and record-keeping.

However, there are substantial differences in regulations needed to assure quality in large commercial labs, as compared to small physician office labs--in the types of tests performed, technology, and personnel needed for the majority of lab procedures performed in smaller POLs.

Regarding the absence of government standards for POLs, many hospitals are reluctant to accept preadmission POL test results and feel compelled to repeat the tests. The Health Industry Manufacturers Association contends that improved test accuracy will come from **technology**--not regulation. HIMA favors voluntary proficiency testing, prompt FDA review of new diagnostic tests, and more study of whether regulation can improve lab quality.

When talking about POLs, a key issue is **the proper use of reagents**, usually determined by the instrument used for the test. Prepackaged test reagents are easy to use and can be stored for a long time, but they are very expensive, can generally be procured from one only one vendor, and may be limited in test variety. Such reagents are frequently used with less costly, semi- or fully automated instruments and are well suited for stat testing and/or low-volume requirements. The cost of these tests is usually prohibitive for doing profiles. Some reagents must be reconstituted to liquid form, they are less costly than prepackaged ones,

and are more suitable for high-volume testing. Reagents and disposables will represent the largest ongoing cost in most cases.

Some analyzers can perform microsample determinations. This may be important to physicians considering equipment for a pediatric or oncology practice where "fingersticks" are often performed. (Note: Many lab directors interviewed by Marketdata's phone survey estimated that 75-90% of fingerstick tests performed by physicians are probably inaccurate.). Quality control systems are essential for POLs, since **the physician performing the tests will be held legally responsible not only for the *interpretation* of the test, but also for its *accuracy*.**

Of almost 7,000 hospitals in the United States, the majority are community or nonfederal hospitals. Community hospitals can be grouped according to ownership: non-profit, investor-owned, and state or local government-operated. While the majority of hospitals are still non-profit, the latest trend is to "corporatization" and the development of multi-hospital systems or chains.

Hospitals are complex institutions. Clinical laboratories come under the scope of "ancillary services", which come under the authority of the hospital administrator, who in turn reports to a board committee. Generally, the various departments include the following: 1) medical staff departments, 2) financial, 3) nursing, 4) ancillary, and 5) support.

Medical laboratory technicians perform a variety of clinical lab procedures under the direction of a qualified physician and pathologist or medical technologist. **Medical technologists** work in the hospital's clinical lab and are involved in testing procedures in areas such as hematology, serology, and chemistry. **Microbiologists** work in the clinical lab department of large hospitals, determining the structures of bacteria, viruses and other organisms, and making cultures.

Medical technologists perform or supervise various tests in clinical areas that include: hematology (blood), cytology (cells), parasitology (parasites), and nuclear medicine. By the mid-1980s it was estimated that over 150,000 medical technologists existed nationwide. Their salaries range from the mid-20s up, and technologists may advance to supervisory positions and administrative posts. One drawback to working in a hospital, particularly large ones, is that the technologist may feel professionally isolated because both the laboratory and departments within the lab are separated from each other, with associated problems in communications. Also, advancement opportunities may be limited, due to low turnover in the top positions.

FINDINGS OF 1988 SURVEY OF LAB DIRECTORS

Marketdata conducted a national telephone survey of independent commercial Lab Directors and Supervisors, during March/April 1988. Lab Directors were asked the following questions, and interviewed at length:

- * What are the biggest challenges or problems faced by your lab or company today ?
- * How do small, independent commercial labs compete effectively with larger regional or national chain operators ?
- * What special marketing techniques or policies does your lab use to distinguish itself and survive ?
- * Are there any lab instruments that produce a significant number of problems, regarding calibration, accuracy, etc. ?
- * What is the extent of competition from physician in-office testing ? What types of tests do they typically perform ?
- * How have Medicare/Medicaid payment schedules and regulatory actions affected your business ?
- * What is your overall outlook for the business in the short term and long term ?

Based on in-depth conversations with over 100 Lab Directors nationwide, following are the major findings.....

The most critical problems faced by independent clinical laboratories, are, in order of importance.....

- 1) Finding and retaining qualified technologists/staff. Salary levels are still inadequate to compensate technicians for the amount of training they must have, workloads, and the increasingly common fear of catching AIDS when working with specimens.
- 2) Coping with regulatory agency actions, such as the reduced rate Medicare reimbursement fee schedule, and keeping cost-competitive. Payments have been cut to 50% of what it costs labs to actually do the work, and most Lab Directors foresee that percentage going lower. The government has also made it virtually mandatory to accept the new fee schedule. This is a big factor in whether labs can continue to provide quality service to Medicare patients. Most of the good labs will probably not be interested in Medicare business in the future.
- 3) Competition from totally unregulated physician in-office testing. These doctors can charge whatever they feel like charging. They are performing complete blood counts and chemistry profiles (commonly called

"smacks"--a series of 20 tests), as well as sugar/glucose and cholesterol tests.

- 4) Time wasted performing unnecessary procedures. Routine tests such as cholesterol many times are ordered as a public overreaction to a newspaper article or TV news story--all of a sudden everyone wants one, whether they need it or not.

Competing With Larger Labs And Chain Operators:

Virtually all independent lab directors interviewed reported that they could not compete head-to-head with the larger lab chains (Damon, SmithKline, Roche, etc.) on a **volume** or **price** basis (for Pap smears, cholesterol, other high-volume tests). Rather, the lab has to distinguish itself in some way, either by specializing in a particular area (i.e. radioimmunoassays, infertility, etc.), by superior service, or by serving the local community with personalized service.

Larger lab chain companies are the only ones that can afford the capital needed to purchase the very large instruments that perform very high volume testing, in a short amount of time.

Following are several actions small labs take to more effectively "market" their services.....

- * Fast turn-around time (within a few hours). Many larger operations cannot offer service this rapidly.
- * They promote their proximity to patients' offices--local, personalized service, outbound service (free pick-up & delivery to nursing homes, home care in general).
- * "House call" service, frequently used by **hospital** labs, where they provide outpatient lab services to people restricted to their homes. After the physician writes a request for a test, the patient calls the hospital's lab, and they send a technologist to the patient's home to obtain the specimen, brought back to the lab for processing. The results are then sent to the patient's physician. A nominal fee is charged for the service.

A "smack" (chemistry profile) may cost only \$5 from a **reference** laboratory, cheaper than a small lab could do it in-house. The reference lab will supply all the materials. The small lab just has to spin the sample and repackage it.

The **in-hospital** labs also report using a variety of techniques to more effectively market their services and run their labs more efficiently, such as.....

* **Drawing up Marketing Plans**

- * Installing automated instruments and microcomputers
- * Submitting competitive bids for reference labs
- * Volume discounts - joining other hospital labs in group purchasing
- * **Market segmentation** of customers (i.e. industrial accounts - drug abuse testing, HMOs, the general public)
- * Price discounts
- * Regulation of test ordering by clinicians
- * Mergers with other labs

Lab Technicians/Staff - Recruitment & Retention

Years ago, lab workers could get a job in a lab with only six months' education beyond high school. Now, they must have a minimum of a 2-year degree, and many times 4-6 years education, depending on the position in the laboratory. But, salaries have not advanced correspondingly with the levels of education demanded. Labs are losing many people in the industry for that reason. Also, there is a real fear of the AIDS virus--there are rumored cases of lab technologists that have caught AIDS. (There are documented cases of **nurses** contracting the disease, but Marketdata cannot confirm if any lab workers have indeed been infected by working with specimens).

New York State is coming down harder on labs, requiring proficiency testing exams. But New York is the exception rather than the rule. In other parts of the country, labs are not even regulated by the *federal* government. However, lab worker **proficiency testing** is mandated for all states in order to meet Medicare requirements. But, simply because labs have the **capability** to meet requirements is no guarantee that programs are actually followed or implemented.

Most lab directors feel that lab technicians' salaries are still too low, and they are not being adequately compensated for the extra risk they take today in handling AIDS-related tests. Also, the small, independent labs do not have labor unions to fight for workers' pay and benefits.

Many labs report losing their part-time female lab workers, more of whom are working at full-time jobs or are having children and staying at home.

The new "baby boomlet" cannot be overlooked. Many women that postponed child rearing until their early-mid 30s are now having children, and are dropping out of the workforce, at least in the short-term (next 5 years). Labs will have to recognize this demographic trend and adjust their recruitment efforts accordingly.

Despite the feeling that salaries are still too low, they are not exactly at poverty levels either. For example, it is commonplace to find classified ads run regularly in the Northeast or Mid-Atlantic areas of the country which offer medical technologists the following:

- * Starting salary of \$27-30,000 (experienced)
- * Health & life insurance
- * Tuition reimbursement programs
- * Holiday bonus
- * 5 personal holidays
- * Savings/investment plans

Use of Lab Instrumentation

The overwhelming majority of lab directors report that they have no major problems with lab instrumentation on the market today, in terms of reliability and accuracy. The instruments available are pretty sophisticated, and problems are usually reconciled by the manufacturer. Manufacturers also provide training, if needed. They generally have very good technical staffs that answer questions, do troubleshooting, and service instrumentation the same day.

Analyzers used by **physicians**, by nature, have to be more sophisticated and complex, in order to be "user friendly" and designed for ease of operation by staff that may not have the same amount of experience as a licensed lab technologist. However, because they are more sophisticated, proper maintenance, calibration and use of appropriate reagents is even more crucial. Some lab directors expressed a desire that some of the newer high-speed equipment was not as delicate to operate.

Lab Instruments, by nature, have to be reliable because hospitals and other users cannot afford "downtime" that jeopardizes patient care and quick analyses related to critical situations and surgery.

Competition From Physician In-Office Testing

Most lab directors report that they do encounter some competition from doctors that perform their own tests, which include such procedures as: complete blood counts, sugar/glucose tests, chemistry profiles, blood cholesterol tests, uric acid, SMA-6s, triglycerides, etc. Procedures such as hormonal studies and therapeutic drugs are still generally done by labs, not private physicians. But, the percentage of their business lost is really not known. A majority of lab directors feel that physician in-office testing may be hurting rather than helping the industry and its image.

Others feel that the busier group practices really do not have the time to fool around with testing, and training personnel properly. These doctors are probably not even considering performing their own tests, and do not represent a competitive threat to independent labs.

Doctors often are not adequately trained in the proper calibration of the analytical instruments they use, they do not adhere as strictly to cleaning and maintenance procedures recommended, they have no quality control system, are using out-of-date equipment, and they are totally unregulated and uninspected. In addition, the assistants working for them and performing procedures do not have to meet the same educational and proficiency requirements that lab technologists do. They may make errors with too much or too little blood used in the sample, timing, dirty supplies or equipment, etc.

The type of tests performed by physicians varies, usually with the size of the practice. In group practice situations, they may perform the same types of tests as the independent lab. Single doctors may perform only the most basic analyses. They do know how to **interpret** the test results, but the procedures followed, leading up to that test result, are what is in question.

The main reason why lab directors felt doctors are now doing their own testing is **economic**—to increase their income, rather than improving the **accuracy** of test results or gaining more control of the testing.

Future Outlook For The Industry

The majority of lab directors surveyed feel that there may be a smaller number of independent clinical labs operating in the future, but do not foresee their "extinction", as predicted by some industry analysts. There

will always be a need for "stat" labs and fast turnaround service, which the large labs generally cannot provide. Large labs may require that the specimen be recieved by 10 AM to obtain results that same day, whereas a smaller lab may be able to accept it by 3 PM and still get results by the end of that day.

Some labs reported that 18 months ago they received perhaps 30 requests per month for AIDS tests--now it is ten times that amount of activity. New test procedures that are forecast to increase in the future will be in the entire range of infectious diseases, viral and antibody tests. The public is becoming more and more conscious about AIDS every day, and will usually go to a private physician, who in turn uses an independent lab for the test.

Labs are required to obtain a special contract to perform AIDS tests (such as Damon Corp. with a military/government contract). Otherwise, the lab is not permitted to do the test. Highly regulated areas such as new York City and New York State in general are examples of this. The expected volume of AIDS tests in the future will force testing into the hands of more independent labs--the volume going through blood banks and state health departments will become too great for the system to handle.

Another area of future projected growth is in the public awareness of cardiovascular health, and related tests such as: HDLs, cholesterolis, special proteins, globulins, etc.

COMPUTER-SEARCHED ABSTRACTS OF CLINICAL LAB INDUSTRY DEVELOPMENTS

- 82 -

Marketdata contracted the services of a local University center for business research, to perform a custom search of several business databases for this report. The Predicast "U.S. Forecasts" and "PROMPT" databases were searched by SIC code and key words, for articles published about the medical laboratory industry within the past year. Approximately 40 bibliographic "abstracts" were found, and are presented in the following section.

Articles were found that deal with industry consolidation, industry size and growth, company reports, references to other research reports, etc. The publication's name, date the article was published, and page number are given, in case the reader wants further information and would like to track down the full article.

Such business database searches are useful for obtaining comprehensive information about specific markets or industries, very quickly and cost-effectively, generally for \$50-150. And, a company does **not** need its own computer system to access the database. A good University library's staff can perform the search, with delivery of the abstracts within 2 weeks. Abstracts can be printed "on-line" (as you wait) or "off-line" (in 1-2 weeks, printed on better paper-not computer bar-type stock. Off-line abstracts usually cost about 50 cents each (depending on the database searched), on-line is cheaper. You also pay for the connect time and library staff time to get into the database. **All** costs combined still run \$50-150, unless a very large number of abstracts are desired.

DIALOG

DIALOG File 16: PROMT - 72-87/OCT, WEEK 4 (Copr. Predicasts Inc. 1987)

1775166

New UK NIBSC L25m laboratories.

SCRIP-World Pharmaceutical News September 25, 1987 p. 5

United Kingdom: National Institute Biological Standards and Control has opened a UKL25mil medical research facility in S Mimms. The NIBSC is the standards lab for medical substances with a biological or living dimension, which cannot be characterised just by chemical and physical features. The new lab will be involved in UK AIDS research, as 1 of the World Health Organisation's 10 centres for AIDS research.

1774388

US clinical labs to consolidate?.

Clinica September 23, 1987 p. 11

US: Clinical lab testing industry's revenues will total \$16-20bil in 1987, according to Smith Barney (US). Hospitals will account for 50% of total revenue, physicians for 25%, and independent labs for 25%. There were over 11,000 federally registered clinical labs in 6/87, including 4,368 Medicare-approved independent labs. There were also 6,658 Medicare-approved hospitals, the vast majority of which have at least a small emergency lab. An estimated 100,000 physicians conduct their own testing. Smaller labs are likely to come under continuing pressure from competitive pricing by the larger companies, as well as from the increase in the number of physician's office labs. Many hospitals are finding it too costly to continue processing tests in their own facilities, and may either form joint ventures with other hospital or independent labs, or offer contracts to independent companies which can manage the hospital business more economically.

1763834

Bear, Stearns & Co Investment Analyst Report on American Medical International, Inc.

CIRR July 2, 1987 p. 5

Research Highlights prepared by C. M. Schaible consisting of 2 pages. Report contains 86-87-88E EPS, 87-88E P-E, 86-87 Third Quarter Analysis - Income Statement, Operating Income.

Documents available from JA Micro, Box 218, Eastchester, NY 10707, 800-227-CIRR (NY 914-793-2130). When ordering refer to fiche number: BSC-47 (87-1292) A; title for NYSSA; date and article title for Investor's Daily. Copyright restrictions apply.

1762557

Hoffman-La Roche forms jv in Japan.

European Chemical News August 31, 1987 p. 12

Medicom (Japan) is a new joint venture operating clinical testing labs. Nippon Roche (Japan), a subsidiary of Hoffman-La Roche (Switzerland), holds 50%, and Sumitomo Chemicals (Japan) and Sumitomo Pharmaceuticals (Japan) jointly hold 50%. The new company has a share capital of Y400 mil, and expects Y300 million turnover in 1988.

DIALOG

DIALOG File 16: PROMT - 72-87/OCT, WEEK 4 (Copr. Predicasts Inc. 1987)

1733412

Bear, Stearns & Co Investment Analyst Report on American Medical International, Inc.
CIRR June 12, 1987 p. 7

Research Highlights prepared by C. M. Schaible consisting of 4 pages. Report contains 86-87-88E EPS, 87-88E P-E, Dividend, Yield, Cash Flow, 86 Summary Capitalization, 84-86-87-88E Revenue Analysis, 84-86-87-88E Income Statement, Chart.

Additional companies named in this report: Hospital Corporation of America; Humana, Inc.; National Medical Enterprises, Inc.

Documents available from JA Micro, Box 218, Eastchester, NY 10707, 800-227-CIRR (NY 914-793-2130). When ordering refer to fiche number: BSC-40 (87-1001) A; title for NYSSA; date and article title for Investor's Daily. Copyright restrictions apply.

1732082

Eberstadt Fleming, Inc Investment Analyst Report on Westmark International, Inc.
CIRR June 12, 1987 p. 1

Report prepared by R. P. Esquivel consisting of 13 pages. Report contains 86-87 Recent Results, 86-87E Quarterly EPS Estimates, 86-90E Earnings Model, 82-89E Ultrasound Market, 86 Patent Monitoring Market, 86-87 Balance Sheet, 86-88E Cash Flow Forecast, 86-90E Return on Equity.

Spinoff from Squibb. 87 EPS Estimate of \$.90. Cash-per-Share Exceeds \$600. No Debt Outstanding. Strong Management. Weakness in Dollar Has Boosted Overseas Sales. Ultrasound Market.

Additional companies named in this report: Squibb Corp.; Spacelabs, Inc.

Documents available from JA Micro, Box 218, Eastchester, NY 10707, 800-227-CIRR (NY 914-793-2130). When ordering refer to fiche number: ECC-09 (87-920) C; title for NYSSA; date and article title for Investor's Daily. Copyright restrictions apply.

1722231

Deal Make Ohio Lab a Division of Calspan.
Buffalo News (NY) July 8, 1987 p. C;5

Systems Research Laboratories (Dayton, Ohio) has been acquired by Arvin Industries. SRL will operate as a division of Arvin/Calspan (Cheektowaga, New York). The employment at the Cheektowaga facility will not be impacted by the acquisition, according to T Hanlon, a spokesman for Calspan. SRL is seen as becoming an addition to Arvin's government research business, with its sales in major Air Force programs which include the national aerospace plan, the new air defense initiatives program and chemical defense programs. The acquisition involved a stock-for-stock transaction in which Arvin issued 1.04 million shares common stock for all outstanding common shares of SRL, which becomes a wholly-owned subsidiary of Arvin. SRL, which has sales of \$63.1 mil/yr, provides government and industrial customers with high-technology services.

DIALOG

DIALOG File 16: PROMT - 72-87/OCT, WEEK 4 (Copr. Predicasts Inc. 1987)

1715681

US clinical testing market.

Research Studies (for further information apply to source indexed) March 1987
p. 1-210

This research study covers market trends and competition in clinical chemistry, immunoassay, microbiology, hematology-coagulation, serology-immunology, urinalysis-fecal analysis and cytology-histology. The report includes sections on AIDS and drugs of abuse, as well as providing information on applications of biomedical technology for diagnosis of disease within the clinical lab. Major market participants are discussed, with their market shares, new products and new technologies included. Market forecast through 1990 are given.

Issued by: Biomedical Business Intl, 17722 Irvine Blvd, Tustin, California, 92680, (714) 838-8350. The cost is \$1,950.

1712643

Damon Expands Clinical Market.

Mass High Tech July 5, 1987 p. 6

Damon Clinical Laboratories (Needham, Massachusetts) will manage St Barnabas Hospital's clinical lab, which process 10,000/day diagnostic tests. The agreement will add some \$2.6 mil/yr to Damon's revenues and will provide expanded diagnostic testing for the hospital, located in the Bronx, New York. The New York clinical diagnostic testing market is worth some \$200 mil/yr. Damon set up a lab in New York, New York, in 12/86 under an agreement with Beth Israel Medical Center, an acute-care teaching hospital like St Barnabas. The Damon clinic at Beth Israel provides clinical testing both to the hospital and to other area physicians and hospitals. The novel joint venture arrangement is expected to become a trend in the cooperation between non-profit hospitals and businesses. Damon plans to establish such long-term relationships with hospitals and medical centers for mutually beneficial services that are more efficient and cost less. Damon generates some \$110,000/yr from the hospital market.

1649597

Two Pontiac health-care firms merge.

Crain's Detroit Business (MI) June 14, 1987 p. 27

Apple Medical (Pontiac, Michigan) has merge with Advanced Medical and Research Center (Pontiac, Michigan) to compete with hospitals. Apple Medical, a company which sells and rents durable medical equipment, has gotten together with Advanced Medical, a clinical lab which serves doctors and hospitals, in an effort to increase their market share. Advanced Medical's 16 employees will attempt to encourage its physician's clients to purchase or lease durable medical equipment from Apple. In fiscal year 1986 the company had revenues of \$21 million and 500 employees. The company has about 2,000 physicians and hospital clients, mainly in Michigan. Advanced Medical is hoping that the move will help it offer more services to its clients. Apple had revenues of \$1.2 million in FY86. The company employs 25 people. Apple competes against large hospitals which own or have joint ventures with other durable medical equipment companies. Apple decided to work with Advanced Medical because of its outstanding reputation and clients throughout the state.

DIALOG

DIALOG File 16: PROMT - 72-87/OCT, WEEK 4 (Copr. Predicasts Inc. 1987)

1640889

PaineWebber Investment Analyst Report on American Medical International, Inc.
CIRR April 10, 1987 p. 1

Report prepared by D. J. Lothson consisting of 4 pages. Report contains Quarterly Segment Data 86-92E, Operating Expense Trends 84-87.

Documents available from JA Micro, Box 218, Eastchester, NY 10707, 800-227-CIRR (NY 914-793-2130). When ordering refer to fiche number: PWC-20 (87-578) G; title for NYSSA; date and article title for Investor's Daily. Copyright restrictions apply.

1639153

Bear, Stearns & Co Investment Analyst Report on American Medical International, Inc.
CIRR April 3, 1987 p. 7

Research Highlights prepared by C. M. Schaible consisting of 3 pages. Report contains 86-87 Revenue Analysis, 86-87-88E EPS, 87-88E P-E, Chart.

Additional companies named in this report: Humana, Inc.; Hospital Corp. of America.

Documents available from JA Micro, Box 218, Eastchester, NY 10707, 800-227-CIRR (NY 914-793-2130). When ordering refer to fiche number: BSC-27 (87-525) A; title for NYSSA; date and article title for Investor's Daily. Copyright restrictions apply.

1620926

Merrill Lynch Canada, Inc Investment Analyst Report on M D S Group Health, Ltd.
CIRR February 17, 1987 p. 1

Report prepared by R. Jones consisting of 6 pages. Report contains 86A 87E 88P EPS, 86A 87E 88P P-E Ratio, 86 Statistical Comparison, 82-86 Financials.

In October of 85 it completed a \$30 million private placement of floating-rate secured debentures to three trust companies.

Documents available from JA Micro, Box 218, Eastchester, NY 10707, 800-227-CIRR (NY 914-793-2130). When ordering refer to fiche number: MLCC-03 (87-438) B; title for NYSSA; date and article title for Investor's Daily. Copyright restrictions apply.

1613476

Singapore hospital/industry venture.
Marketletter (formerly IMS Pharma- ceutical Marketletter) March 23, 1987 p. 16

Medlux Referral Laboratories (Singapore), a medical laboratory service firm, has been jointly formed by Medlux (Sweden) (60%) and National University Hospital (NUH) (Singapore) (40%). The facility will supply more specialized tests, such as hormonal assays, and will develop new laboratory medicine methods, equipment and diagnostics.

DIALOG

DIALOG File 16: PROMT - 72-87/OCT, WEEK 4 (Copr. Predicasts Inc. 1987)

1596807

L F *Rothschild, Unterberg, Towbin Investment Analyst Report on International Clinical Laboratories, Inc.

CIRR February 2, 1987 p. 1

Report prepared by J. E. Millsap consisting of 8 pages. Report contains Financials '86-88P, Financial and Stock Market History '79-86, Capitalization, Quarterly Sales and Earnings '86-88P, Consolidated Balance Sheets, Statement of Change In Financial Position '84-88P, Stat Profile '79-87E.

Investment viewpoint, Lifetrac Chemosensitivity Assay, CSA case Study, conclusion.

Documents available from JA Micro, Box 218, Eastchester, NY 10707, 800-227-CIRR (NY 914-793-2130). When ordering refer to fiche number: LFRC-11 (87-261) B; title for NYSSA; date and article title for Investor's Daily. Copyright restrictions apply. Price category "A".

1596690

Morgan, Olmstead, Kennedy & Gardner, Inc Investment Analyst Report on American Medical International, Inc.

CIRR December 16, 1986 p. 1

Report prepared by D F Saks consisting of 6 pages. Report contains 85-88 Financial Highlights, 85-86 87E Quarterly Comparisons, 87-88E P-E Ratio, 86 87-88E EPS, Chart.

Documents available from JA Micro, Box 218, Eastchester, NY 10707, 800-227-CIRR (NY 914-793-2130). When ordering refer to fiche number: MQKC-07 (87-244) D; title for NYSSA; date and article title for Investor's Daily. Copyright restrictions apply. Price category "A".

1596680

Morgan, Olmstead, Kennedy & Gardner, Inc Investment Analyst Report on Biotherapeutics, Inc.

CIRR October 22, 1986 p. 1

Report prepared by D F Saks consisting of 13 pages. Report contains 87-88E P-E Ratio, 86A 87-89E EPS, 86A 87-90E Financial Estimates, Charts.

Intends to establish nationwide network of cancer research laboratories in conjunction with leading oncology physician groups. Cancer patients are currently being treated by three conventional modalities-radiation, Chemotherapy or Surgery. Over five million Americans alive today have cancer.

Documents available from JA Micro, Box 218, Eastchester, NY 10707, 800-227-CIRR (NY 914-793-2130). When ordering refer to fiche number: MQKC-06 (87-243) G; title for NYSSA; date and article title for Investor's Daily. Copyright restrictions apply. Price category "A".

1591897

Company news in brief: Biodecision opens new clinical research subsidiary.
SCRIP-World Pharmaceutical News February 18, 1987 p. 9

Biodecision Labs N Carolina has been formed by Biodecision Laboratories to
(cont. next page)

DIALOG

DIALOG File 16: PROMT - 72-87/OCT, WEEK 4 (Copr. Predicasts Inc. 1987)

support clinical research currently performed by Biodecision, including computerized, clinical investigator network.

1589151

Biodecision Laboratories.

Drug & Cosmetic Industry March 1987 p. 67

Biodecision Labs of North Carolina has been formed as a new subsidiary of Biodecision Labs to support all areas of clinical research performed by the parent.

1579336

Bear, Stearns & Co Investment Analyst Report on American Medical International, Inc.

CIRR January 16, 1987 p. 7

Research Highlights prepared by C M Schaible consisting of 4 pages. Report discusses and/or contains New England Journal of Medicine;84-86 87-88E Historical and Projected Operating Results, 86-87 First Quarter Analysis, 86-88 EPS, 87-88 P-E.

Additional companies named in this report: Rand Corp.

Documents available from JA Micro, Box 218, Eastchester, NY 10707, 800-227-CIRR (NY 914-793-2130). When ordering refer to fiche number: BSC-04 (87-26) A; title for NYSSA; date and article title for Investor's Daily. Copyright restrictions apply. Price category "A".

1579241

*L F *Rothschild, Unterberg, Towbin Investment Analyst Report on American Medical International, Inc.*

CIRR January 21, 1987 p. 25

Notes For Portfolio Managers prepared by M. L. Vignola consisting of 4 pages. Report contains Financials '86-88P, Operations By Business Segment '85-86, Consolidated Statement of Income '85-86.

Documents available from JA Micro, Box 218, Eastchester, NY 10707, 800-227-CIRR (NY 914-793-2130). When ordering refer to fiche number: LFRC-02 (87-71) I; title for NYSSA; date and article title for Investor's Daily. Copyright restrictions apply. Price category "A".

1577694

PaineWebber Investment Analyst Report on American Medical International, Inc.

CIRR January 10, 1987 p. 1

Report prepared by D. Lothson consisting of 7 pages. Report contains EPS, P-E Ratios, Quarterly Income Stmt '84-'87, Share Price Performance Graph, Operating Expense Trends '84-'87, Quarterly Business Segment Data '84-'87, Quarterly Hospital Utilization Data '84-'87, '86-'91 Revenue and Income Model.

Flat 1st Q earnings. Good progress in controlling operating expenses. Full year EPS projected at \$1.40. Fiscal '88 EPS Could rise to \$1.70. Expect stock and hospital management group to continue to lag market performance.

(cont. next page)

DIALOG

DIALOG File 16: PROMT - 72-87/OCT, WEEK 4 (Copr. Predicasts Inc. 1987)

Additional companies named in this report: National Medical Enterprises.

Documents available from JA Micro, Box 218, Eastchester, NY 10707, 800-227-CIRR (NY 914-793-2130). When ordering refer to fiche number: PWC-03 (87-124) N; title for NYSSA; date and article title for Investor's Daily. Copyright restrictions apply. Price category "A".

1571023

L F *Rothschild, Unterberg, Towbin Investment Analyst Report on Nichols Institute

CIRR December 10, 1986 p. 59

Notes for Portfolio Managers prepared by J. Millsap consisting of 3 pages. Report contains Stats: EPS, A-E Ratio, Profile.

Documents available from JA Micro, Box 218, Eastchester, NY 10707, 800-227-CIRR (NY 914-793-2130). When ordering refer to fiche number: LFRC-83 (86-1911) O; title for NYSSA; date and article title for Investor's Daily. Copyright restrictions apply. Price category "A".

1570946

L F *Rothschild, Unterberg, Towbin Investment Analyst Report on International Clinical Laboratories, Inc.

CIRR November 12, 1986 p. 59

Notes For Portfolio Managers prepared by J. E. Millsap consisting of 3 pages. Report contains Stats: Financials '86-88P, Stats '79-86.

Additional companies named in this report: Health America; Maxicare; CIGNA.

Documents available from JA Micro, Box 218, Eastchester, NY 10707, 800-227-CIRR (NY 914-793-2130). When ordering refer to fiche number: LFRC-77/78 (86-1905/1906) Q; title for NYSSA; date and article title for Investor's Daily. Copyright restrictions apply. Price category "A".

1570929

L F *Rothschild, Unterberg, Towbin Investment Analyst Report on Nichols Institute

CIRR November 5, 1986 p. 111

Notes For Portfolio Managers prepared by J. E. Millsap consisting of 4 pages. Report contains Stats: Financials '85-87P, Recent Results '85-86, Revenue Mix '85-86 Sales and Earnings '84-87P, Financial Projections '83-87P.

Documents available from JA Micro, Box 218, Eastchester, NY 10707, 800-227-CIRR (NY 914-793-2130). When ordering refer to fiche number: LFRC-76 (86-1904) DD; title for NYSSA; date and article title for Investor's Daily. Copyright restrictions apply. Price category "A".

1569903

L F *Rothschild, Unterberg, Towbin Investment Analyst Report on American Medical International.

CIRR October 15, 1986 p. 41

(cont. next page)

DIALOG

DIALOG File 16: PROMT - 72-87/OCT, WEEK 4 (Copr. Predicasts Inc. 1987)

Notes For Portfolio Managers prepared by M. L. Vignola consisting of 4 pages. Report contains Stats: Financials '85-87P, Consolidated Statement of Income '85-86, Operations By Business Segment '85-86.

Additional companies named in this report: Bass Brothers.

Documents available from JA Micro, Box 218, Eastchester, NY 10707, 800-227-CIRR (NY 914-793-2130). When ordering refer to fiche number: LFRC-69/70 (86-1897/1898) L; title for NYSSA; date and article title for Investor's Daily. Copyright restrictions apply. Price category "A".

1565802

Companies: company news in brief: Hubber-letters of intent signed.

SCRIP-World Pharmaceutical News January 9, 1987 p. 11

Hubber (Spain), a pharmaceuticals firm, will have 75% acquired by ICN (US). The value of the deal has not been disclosed. The Spanish government will retain 25% of the firm. A letter of intent for the acquisition has been signed.

1556245

Medical Labs, Trusted As Largely Error-Free, Are Far From Infallible.

#Wall Street Journal 3 Star, Eastern (Princeton, NJ) Edition February 2, 1987 p. 1, 18

Medical researchers criticize many medical testing labs for providing inaccurate results. In many states, clinical labs that test body fluids and tissues aren't licensed, and thus aren't screened by regulators. In states that require licensing, proficiency requirements and scrutiny by regulators vary widely. Americans spend about \$20 bil/yr on clinical lab tests, which are often a great help in diagnosing and treating disease. But many patients mistakenly regard such tests as infallible, even though human and mechanical error is fairly common and every lab produces some inaccurate test data. The problem affects labs in prestigious hospitals and doctors' offices as well as independent sites. Though mistakes on lab tests aren't as dangerous as incompetent medical treatment, serious consequences can result: Undetected cancer can spread, conditions that could be treated if detected go unchecked, and employees can lose their career if mistakenly identified as a drug user. Though Congress passed the Clinical Laboratories Improvement Act in 1967 to combat the problem, the law covers only labs conducting interstate business. Legislators hoped it would be used by states as a model for reform but only half of the states have enacted lab regulations, and much of it is feeble.

1551194

In brief: Nichols Institute.

MDDI Reports Gray Sheet January 5, 1987 p. 10

Medlab will be acquired by Nichols Institute for \$5.3mil in cash and notes. Medlab, which had sales of \$6.5 million in fiscal year 1986 (ended 9/30), is a clinical lab serving hospitals and physicians in the Portland, Oregon, area. It will become part of Nichols' Network subsidiary, an operator of regional non-esoteric labs in San Diego and San Pedro, California.

DIALOG

DIALOG File 16: PROMT - 72-87/OCT, WEEK 4 (Copr. Predicasts Inc. 1987)

1551139

Smithkline Bio-Science Labs sales reach \$372 mil in 1986, up 8.8%; firm claims 90% test completion rate within 24 hours, 98% within 48 hours.

MDDI Reports Gray Sheet December 22, 1986 p. 4

SmithKline Bio-Science Labs (SKBL) expects sales to rise 8.8% to \$372mil in 1986 vs 1985, according to pres H Groome. SKBL is the 1st and largest nationwide clinical lab network. SKBL leads the field in 1986 revenues ahead of Roche Bio-Medical (estimated \$255 mil), Metpath (\$215 mil), National Health Labs (\$189 mil), International Clinical Labs (\$168 mil) and Damon (\$98 mil). These 6 companies accounted for 52% of the \$2.4 billion national reference lab market in 1986. SKBL offers a 24-hr turnaround rate of 90% and a 48-hr turnaorund rate of 98% for all specimens. Significant growth areas will be AIDS screening, which is not currently a high volume test but is doubling every 6 mo, and new market needs such as industrial drug testing.

1548206

Popularity of Novel Health Tests Worries Many Doctors, Regulators.

Wall Street Journal 3 Star, Eastern (Princeton, NJ) Edition January 21, 1987
p. 23

Independent testing labs that provide health and fitness tests are coming under fire from doctors, regulators and insure.s, who claim the tests are often unnecessary, innacurate or misleading. Independent testing labs currently perform some 35% of health testing in the US, and are growing too fast to be properly inspected by regulators. All too often, services such as hair analyses and stress tests are part of a sales pitch for pricey nutrition supplements or marketing tools used by health clubs to attract customers. Doctors complain that the technicians who administer the tests are not qualified to evaluate the results, which are often inaccurate anyway. For example, the New York Attorney General obtained a court order to stop Bio Health Centers from doing mail-order blood tests after it couldn't tell the difference between a sample of cow and human blood. When an investigator sent a sample of cow blood for testing at the lab, the company responded that the patient was allergic to 22 substances, including cow's milk and cottage cheese. Another lab, Doctor's Data Laboratories (Chicago, Illinois), offers various mail-order hair analyses, and claims the results are valuable measures of fitness. State authorities say they can't prevent the tests because the lab doesn't peddle follow-up nutrition supplements. A number of health clubs also offer stress tests, which measure electrical impulses created by heartbeats while the patient is on a treadmill. Medical experts say a simple blood-pressure test can yield the same results at only a fraction of the \$250 that many fitness clubs charge.

1543065

UK company news:JS Pathology expansion as profits rise 30%.
Financial Times (London Edition) November 27, 1986 p. 28

Matpath UK, a drugs wholesaler, will be acquired by JS Pathology (UK), a medical laboratory, from Corning Glass Works (US) for UKL4.6 mil. JS Pathology will pay further installments up to UKL2.5 million depending on financial performance in FY87.

DIALOG

DIALOG File 16: PROMT - 72-87/OCT, WEEK 4 (Copr. Predicasts Inc. 1987)

1526148

PaineWebber Investment Analyst Report on Moore Medical Corp .
CIRR October 20, 1986 p. 1

Report prepared by J. D. Adams consisting of 3 pages. Report contains Stats: Financials 80-88E.

Documents available from JA Micro, Box 218, Eastchester, NY 10707, 800-227-CIRR (NY 914-793-2130). When ordering refer to fiche number: PWC-48 (86-1275) F; title for NYSSA; date and article title for Investor's Daily. Copyright restrictions apply. Price category "A".

1520565

Crackdown on drug use turns into big business.
San Francisco Business Journal (CA) November 24, 1986 p. 1

PharmChem Laboratories (Menlo Park, California) conducts 9,000 work place drug tests/mo, accounting for 15% of business in 1985; the firm expects employee drug tests to bring in 25% of its business in early 1987. In 1984, the firm had 5 corporate clients and now has 200. Over 30% of the Fortune 500 require pre-employment or workplace drug tests and analysts say the US market for the tests, now at \$80 mil, will double by 1990. Syva, a subsidiary of Syntex (Palo Alto, California), has seen sales of its drug test kit rise to \$40 million in 1985. Critics say most clinical labs are not certified and hospitals usually do not have the forensic experience needed to verify test results.

1476068

Scripps, Johnson & Johnson OK \$70 million pact.
San Diego Union (CA) October 8, 1986 p. SecA,1

Johnson and Johnson (New Brunswick, New Jersey) will give Scripps Clinic and Research some \$70mil in 1987-97 for biomedical R&D. The agreement continues a 5-yr relationship between the company and the foundation. It gives Johnson and Johnson first option for commercial applications of vaccines or diagnostics made possible by Scripps (San Diego, California) research. Johnson and Johnson is currently testing several possible products that resulted from Scripps research, primarily in diagnostics. The new award will go towards general research, with no strings attached. Scripps Clinic and Research Foundation signed a 1985 agreement with PPG Industries (Pittsburgh, Pennsylvania) worth \$120 million over 15 years to develop new agriculture products such as herbicides. Part of that award has gone toward a new \$10 million wing of the molecular biology building that will be completed in 1987. Both company arrangements are the same, excepting that Johnson and Johnson is interested in diagnostics and therapeutics, while PPG wants agrichemicals. Scripps currently receives some \$60 mil/yr in federal research funds, primarily from the National Institute of Health. In 1985, private gifts and grants totaled some \$20.3 mil.

DIALOG

DIALOG File 570: PTS MARS - 84-87/Oct 28 (Copr. Predicasts Inc. 1987)

0231704

The Agency Beat: Scripps clinic picks HHC Direct

DM News June 1, 1987 v. 9 no. 11 p. 20

Scripps Clinic & Research Foundation (La Jolla, CA) has switched its \$1 mil direct marketing fundraising account to HHC Direct from Blum Assoc. HHC is a division of H Higgins & Co. SC&RF, an independent medical research center, reportedly moved its account because it wanted a local agency to handle its account.

PRINTS

User:002466
DIALOG

P054: PR 3/5/1-2

Item 1 of 2

DIALOG File 81: PTS US Forecasts - 71-87/Sep (Copr. Predicasts Inc. 1987)

1193190 Clinica 86/11/28 P11 United States
Medical Laboratories. perform of. in vitro tests
(hospital,commrc1).

YEAR	% of prodB
1985	88.
1990	80.

GROWTH RATE= -1.9%
Frost & Sullivan
CC=1USA PC=8071000 EC=451

1170742 Chem Mkt R 86/11/17 P9 United States
Medical Laboratories. operating. in physicians offices.

YEAR	000 units
1985	22.5
1990	48.

GROWTH RATE= 16.4%
Rosenbaum, E Little (Arthur D)
CC=1USA PC=8071000 EC=172

COMPETITOR PROFILES

CORNING GLASS WORKS (operates Metpath division)

Corning Glass is a diversified manufacturer of products made from specialty glasses. The company and its 50%-owned affiliates also produce medical products, electronic devices and other items. Business segment contributions in 1986 were as follows:

	<u>SALES</u>	<u>PRETAX INCOME</u>
Specialty materials	18 %	17 %
Electronics & telecommunications	31	45
Health & science	25	29
Consumer products	26	9

MetPath is headquartered in Teterboro, New Jersey. No sales figures could be obtained concerning the MetPath division alone.

Total company sales in 1986 hit \$1.856 billion, up from \$1.691 billion in 1985. Corning stated that in the second quarter of 1987, strong gains were achieved in laboratory testing services at Metpath and Hazelton.

Health and science operations include optical glass lens material, laboratory glassware, Netpath clinical testing services and Hazelton's industrial laboratory services. Equity investments include ventures with Ciba-Geigy, Ltd., A.E. Staley Mfg., and Eastman Kodak.

DAMON CORP.

Damon Corp. was named as a potential takeover target, on April 6, 1988, by executives of American Magnetics Corp, who have acquired a 9.97% stake in Damon. In an SEC filing, the American Magnetics execs disclosed that they have purchased 933,300 shares of Damon's approximately 9.4 million common shares outstanding.

Damon, a Needham Heights, MA-based firm that owns a chain of clinical laboratories, recently became the subject of takeover rumours after Corning Glass Works and SmithKline Beckman Corp. engaged in a bidding

war for one of Damon's rivals, International Clinical Laboratories Inc. American Magnetics, which makes optical character recognition and other electronic products, has no clinical lab business. Analysts said that it may intend to sell its Damon stake in a takeover by another concern rather than to acquire Damon. A Damon spokesman said, "With the buyout of International Clinical, we are the last of the major independent clinical laboratory concerns."

The company is a leader in the clinical diagnostics industry, operating a nationwide network of clinical labs and manufacturing instrumentation and diagnostic products. Contributions by business segments in fiscal 1986, as reported by Standard & Poors, was as follows.....

	<u>Sales</u>	<u>Profits</u> (\$ Millions)
Medical services	66 %	\$8.6
Medical/electronic prods.	21	3.1
Hobby/educational prods.	11	2.5
Damon Biotech	2	-12.4

The company employs 3,150 workers, and foreign revenues represent 3% of total sales.

Medical services includes clinical lab tests in the areas of blood and urine chemistry and electrocardiography, kidney dialysis, and pulmonary function testing. Medical products consist of centrifuges, microtome-crystats, cell washers and accessories. Electronic items include crystal filters and oscillators and delay lines.

Damon Biotech (63% owned) develops and produces biomedical products. Its primary business currently is the contract production of monoclonal antibodies for Hoffmann-LaRoche and other firms. In March 1987, Damon's Biotech unit and SmithKline-Beckman announced an agreement under which Damon will produce the thrombolytic agent tissue plasminogen activator (t-PA). In January, Damon Biotech signed an \$8.5 million agreement with Yamanouchi Pharmaceutical Co. of Japan, under which Damon will produce t-PA for this Japanese company.

In June 1987 the company agreed to manage the clinical laboratory at St. Barnabas Hospital in the Bronx, N.Y. The agreement represents about \$2.6 million in yearly revenues. In late 1986 Damon agreed to manage the clinical lab at Beth Israel Medical Center in New York City.

Spurred by strong growth in clinical lab business, analysts expect sales for fiscal 1988 to advance strongly. For the year ended Aug. 31, 1987, Damon earned \$2 million, or 21 cents a share, on sales of \$176.2 million. For the first quarter ended Nov. 30, the company earned \$1.3 million, or 14 cents a share, on sales of \$47.5 million.

Following is a 1980-86 financial summary of Damon Corp.....

	<u>Revenues</u>	<u>Net Income</u>	<u>Capital Expend.</u>	<u>Net As A % Revenues</u>	<u>% LT Debt of Capital</u>
	(\$ Millions)				
1980	\$137	\$2.31	\$9.3	1.7 %	31.3 %
1981	146	(0.02)	8.2	NM	37.4
1982	127	(2.57)+	5.9	NM	45.5
1983	118	0.60	5.0	0.5	28.6
1984*	127	1.61	12.7	1.3	28.1
1985	129	(3.50)	9.7	NM	30.1
1986	148	(2.51)	7.6	NM	28.7

* Reflects merger or acquisition.

NM - Not meaningful

+ Incl. equity in earnings of nonconsol subsidiary

Analysts estimate that Damon's lab business contributes more than 50% of its pre-tax earnings. The business has grown rapidly during the past year, leargely through formation of joint ventures with large hospitals that offer lab tests. Damon has also benefited recently from U.S. Army contracts for AIDS testing.

Analysts also feel that Damon will probably benefit from synergies between its biotech and clinical lab divisions by 1990-92. The Biotech subsidiary is collaborating with the National Cancer Institute to develop tests for determining the sensitivity of various cancers to chemotherapeutic agents. Products such as Encapcel will likely reach the market by the early 1990s, and should have a sizeable impact on Damon Biotech's sales, as well as generate new business for the clinical labs.

Damon should be well positioned to reap the rewards of vertical integration into the field of disease diagnosis. Company profits should be lifted substantially over the next 3-5 years, due to the expansion of the clinical labs division, the launching of more diagnostic instruments by the medical products segment, and the introduction of diagnostic tests and therapeutic agents.

INTERNATIONAL CLINICAL LABORATORIES/SMITHKLINE BECKMAN

Corning Glass Works agreed to drop out of a bidding war with SmithKline Beckman Corp. (April 4, 1988) for ICL, by selling its stake in the company to SmithKline. Corning said it terminated its \$35-per-share tender offer for ICL and will sell its three million shares to SmithKline for \$26 each under an option agreement with International Clinical, giving Corning an overall \$33 million profit.

The sale of Corning's stake in ICL is subject to certain conditions, including the SmithKline not reduce its \$37 -a-share offer.

Corning reached a definitive agreement on March 8 to acquire the Nashville, TN-based firm for \$260 million, or \$26 a share. But Corning raised its bid to \$35 after SmithKline stepped in with a late-entry bid of \$32 a share. SmithKline later raised the bid to \$37.

Corning looked to International Clinical to expand its medical lab business. The acquisition would have doubled Corning's sales in the testing business and given it market-share parity with SmithKline. Corning, which makes specialty glass and ceramics, consumer housewares and telecommunications products, also has its Metpath Inc. subsidiary, which operates 13 clinical-testing labs primarily in the Northeast.

SmithKline, the large pharmaceutical and health product company, was intent on topping Corning's offers to retain its leadership in the fast-growing \$13 billion laboratory industry. International Clinical operates 13 labs, on the West Coast and in the South.

Analysts say that there are thousands of small independent labs, but **six major companies control 40% of the market. In addition to SmithKline, Hoffmann-LaRoche, Corning and International Clinical, they include Revlon Inc.'s National Health Labs and Damon Corp.'s Damon Clinical Labs.**

After a slow start in the 1970s, SmithKline's business has shown considerable growth in recent years. Sales last year reached \$430.7

million, about 10% of its total sales of \$4.3 billion. Analysts estimate profit for the unit at 12% of sales. In 1978, SmithKline's lab business had sales of \$43.9 million, less than 5% of total sales of \$1.1 billion. Harry C. Groome III, President of SmithKline Bioscience Labs, said profit at the unit has been growing at a rate higher than 15% annually.

Philadelphia-based SmithKline said that its \$400 million bid remains in place and urged ICL's board to approve the offer, which expires at 12:01 a.m. April 21st. The SmithKline offer is contingent upon the tendering of at least a majority of ICL's 10 million common shares and share equivalents outstanding. ICL said it will meet with SmithKline to negotiate a definitive merger agreement. The Corning-SmithKline agreement also resolves possible legal claims between the former rival bidders.

Following is a 1980-86 financial summary of SmithKline Beckman, as reported by Standard & Poors.....

	<u>Sales</u>	<u>Net Income</u>	<u>Net As % Sales</u> (\$ millions)	<u>Capital Expend.</u>	<u>Return On Assets</u>
1980	\$1,772	\$308	17.4 %	\$147	21.5 %
1981	1,985	370	18.6	220	21.5
1982	2,969	455	15.3	305	17.5
1983	2,835	486	17.1	233	16.1
1984	2,949	500	17.0	226*	16.1
1985	3,257	514	15.8	206*	16.1
1986	3,745	521	13.9	203*	14.3

*Net of current year retirement and disposals.

Business segment contributions in 1986 broke down as follows.....

	<u>Sales</u>	<u>Profits</u>
Therapeutics	62 %	80 %
Eye & skin care	12	12
Diagnostics/analytical	26	8

NATIONAL HEALTH LABS (Revlon)

National Health Laboratories Inc. (La Jolla, CA) is a wholly-owned subsidiary of the conglomerate: the Revlon Group, Inc. of Edison, NJ. NHL is one of the leading clinical diagnostic laboratory companies in the United States, encompassing over 40 regional reference labs and patient service centers. Local labs provide services to physicians, hospitals, university medical centers and government health agencies. Over 17 million tests are performed annually, for 12,500 clients.

NHL operates a network of over 100 clinical labs and sales service facilities, located in over 77 cities and 26 states, and the firm's system is comprised of four basic types of facilities:

- * esoteric labs
- * regional reference labs
- * satellite (STAT) labs
- * sales service offices (ports)

Esoteric labs (such as Vienna, Virginia and Dallas, TX) perform infrequently requested tests that most labs are not set up to do. Regional reference labs (Plainview, Miami and Phoenix) perform a wide variety of routine and esoteric tests, and serve as parent laboratories for sales offices and satellite labs (Little Rock, Pasadena, Cleveland) who refer all or most of their work to a regional lab.

NHL claims to have a staff of over 2,000 technical and ancillary workers, including over 60 Board Certified Pathologists and Ph.D. Clinical Chemists. NHL participates in proficiency testing programs, including those administered by the following agencies: CDC, College of American Pathologists, Amer. Assoc. of Bioanalysts, and the Amer. Assoc. for Clinical Chemistry. Quality control is stressed highly, and NHL's internal Scientific Affairs group inspects each lab at least three times per year.

Some of the quality control actions NHL takes to ensure accuracy and reliability include the following.....

- * Blind resubmission of patient specimens.
- * Proficiency testing-in 1987 NHL labs participated in about 2000 surveys and performed 28,000 survey analyses.
- * Internal inspections- a program in place since 1978, unannounced inspections followed by an exit interview with the lab director, where a preliminary plan of correction is developed.

- * Each section of the lab is headed by a Medicare certified supervisor, and NHL's ratio of technologists to technical staff is well above the Medicare recommended acceptable ratio of 1 to 3.
- * Reference labs are where the newest tests are first introduced, following a complete evaluation of reproducibility, accuracy, and clinical usefulness.
- * All labs are equipped with automated instrumentation for chemistry panels, hematology including WBC differentials, therapeutic drug monitoring, and other tests adaptable to automated analyzers.
- * Computerized data management—its system flags abnormal values.
- * "Panic" Values—each lab maintains a list of "panic" values for critical analytes.
- * Test repeat policy.

The firm is currently concentrating on the development of new radioimmunoassay techniques, improvement of its current radioimmunoassay testing capabilities, and the expansion of its test offerings in endocrinology and immunology.

Revlon also owns Barnes-Hinds, Inc. a major manufacturer of optical equipment and contact lenses and related products, as well as Max Factor & Co. and Coburn Optical Industries, with U.S. and international offices worldwide.

Revlon's "beauty products" sales amounted to \$1.15 billion in 1986, and "health products & services" accounted for \$458.9 million. Health products/services contributed nearly 42% of total Revlon operating profits in 1986 (before taxes).

ROCHE BIOMEDICAL

Roche Biomedical is owned by the parent, Swiss-based company Hoffmann-LaRoche. Its headquarters is located in Burlington, NC and it is a major player in the clinical lab industry, with 1987 sales estimated at \$318 million, up about 22% from \$260 million the prior year. Roche employs approximately 5,000 workers at its 200 "sites" throughout the United States.

Of these sites, the company operates four **major** labs (in Sacramento, CA, Raritan, NJ, Columbus, OH, and Burlington, NC), as well as 12 **regional** labs. Roche has a presence in all 50 states. It is a full-service clinical lab company that has the capability to perform up to 1,700 different tests, at the rate of 72,000 patient tests **daily**. It is a leader in drug abuse testing,

and performs AIDS, chromosome, and cytogenetics tests as well. The company is cutting back somewhat on its Pap smear test volume, due to the difficulties in finding qualified cytotechnologists. Roche believes that recent NIH announcements will increase Government emphasis on cholesterol testing.

A Roche spokesman believes that the industry will see Congressional legislation aimed at regulating the fast-growing physician in-office testing market. He disputes claims that independent labs will effectively be put out of business within 10 years, due to this competition, because physicians will most likely be required to meet certain minimum standards, and will not be able to perform the more sophisticated analyses handled by large clinical lab chains such as Roche, MetPath, International Clinical Labs, Damon, etc. More likely, physicians will perform only the more basic tests in-house.

THE LAB INSTRUMENTATION MARKET

SUMMARY

According to the U.S. Department of Commerce, U.S. manufacturers shipped over \$610 million worth of clinical lab instruments during 1986, encompassing such instrumentation as: chemistry analyzers--\$257 million, hematology instruments--\$155 million, microbiology--\$24 million, histology--\$77 million, and miscellaneous "other" instruments--worth \$96 million.

In addition, sales of **other** instruments, used in clinical labs, amounted to the following: PH electrodes & meters--\$27 million, ion selective electrodes & meters--\$18.5 million, electrophoresis chambers & supplies--\$35 million, laboratory coulometric analyzers--\$21 million, sample and flow counting systems (manual & automatic)--\$33 million, flame & other type photometers--\$8.7 million (1985), and chromatographic instruments (gas, liquid, other)--\$390.6 million.

Obviously, this is a huge market--over \$1.1 billion in sales annually (at the **manufacturing** level) when adding together all of the above instruments markets. Later on in this section there follow individual overviews of these major laboratory instrument markets, drawn from the opinions and forecasts of well-known industry analysts in the medical/health care instrumentation market, such as the Theta Corp. of Middlefield, CT

There are several dozen **major** players in the field of lab instrumentation. Several hundred total firms (see list at end of this section for names, addresses) manufacture various types of medical, analytical and laboratory instruments and apparatus, but the following are generally the most prominent suppliers.....

Abbott Labs	Finnigan
Advanced Technology Labs	Hewlett-Packard
American Hospital Supply-Baxter	IBM
Applied Research Labs	Johnson & Johnson
Beckman/Altex	Nicolet Instrument
Becton Dickinson	Ortho Diagnostics
Boehringer Mannheim/Bio Dynamics	Perkin-Elmer
Burdick	Phillips
Bruker Instrument	Princeton Gamma-Tech
Coulter Electronics	Siemens
Digilab	Spectra-Physics
DuPont	Varian Associates
ENI	Waters Associates

SPECIFIC LAB INSTRUMENT MARKETS

NEW CLINICAL INSTRUMENTATION FOR THE PHYSICIAN'S OFFICE

New clinical laboratory instrumentation has evolved, in response to a shifting industry/market structure. The diagnostics industry has responded to the shift in testing to the physician's office with increased emphasis on more flexible and economic instruments. These instruments are characterized by ease of operation, computer-driven menus with reporting capabilities, and flexibility in batch, random access, or discrete patient sampling. They cater to the needs of solo or small group practices. Hematology testing has added whole blood platelet counting and automated differential analysis.

In 1987, it was estimated that 13% of lab tests were performed in doctor's offices, and this is expected to double by 1990. Currently, the total market is estimated at \$111 million, and is expected to reach \$183 million by 1990--over 18% annual increases. Manufacturers are seeking ways to reach the growing but fragmented physician office market. The key to this market is the distributor--scrutinized for his territory, number of reps, strength, volume of business, etc.

Major types of in-office testing include: A strep bacteria, sexually transmitted diseases, urinary tract infections, cholesterol levels, hematology, occult blood tests, pregnancy, infectious agents, fungal infections, rubella, rheumatoid factor, mononucleosis, allergy screens, parasitic infections and viral infections.

Major companies serving the physician office market include: Becton Dickinson, Boehringer Mannheim/Bio Dynamics, Burdick, Johnson & Johnson, and Advanced Technology Laboratories.

CLINICAL CHEMISTRY ANALYZERS

This market has long been dominated by an established group of manufacturers. However, recent shifts in the dynamics of this market spell opportunities for new competitors. Theta Corp. projects an annual growth rate of 20% for the doctor's office immunoassay market segment. This high growth may tempt many suppliers to concentrate their efforts on this market--a move that may be shortsighted in view of the increasing need for upgraded technology and replacement units in the higher-volume hospital and commercial laboratory segment.

Reimbursement changes affected this market heavily during the early 1980s, the impact of which still hasn't subsided. The market was initially dominated by hospital and commercial labs. There was an attempt to shift to a small private practice market, but before manufacturers could settle into that new segment the market further reorganized into group practices and specialty labs.

Manufacturers attempted to develop a strategy to effectively market laboratory equipment to physicians but found that many had already updated their labs. Currently, manufacturers are turning to the home testing market, where opportunities are emerging rapidly.

CLINICAL CHROMATOGRAPHY

Chromatography is the largest analytical instrumentation market, and sales for clinical applications constitute a significant market segment. Sales of HPLC systems for clinical use amount to approximately \$25 million, while sales of clinical GC systems total \$20 million.

Over 52,500 **gas** chromatographs were sold by U.S. producers during 1986, worth \$149.5 million at the factory level, while nearly 40,000 **liquid, paper, gel, and TLC** chromatographs were sold, worth \$241 million. The latter category has grown faster--more than doubling in value between 1979 and 1986. Gas chromatograph instrument sales also doubled, from \$72 million in 1976 to almost \$150 million ten years later.

ELECTROPHORESIS

Four main instrument categories make up this research and clinical market:

- * electrophoresis cells
- * power supplies
- * densitometers
- * other accessories

Biotechnology continues to spur electrophoresis sales. The Department of Commerce reports that U.S. producers' shipments of "electrophoresis chambers & supplies" totalled \$35.5 million during 1986, down from \$40.7 million the year before.

FLOW CYTOMETERS

This is a relatively young market. Although research groups have used the technique since 1965, the instrument has only been available

commercially since the late 1970s. This market is expanding, into new applications in: microbiology, oncology, hematology and genetic engineering. The market is divided into three main categories: biomedical, industrial, and clinical. Becton Dickinson, Coulter Electronics and Ortho Diagnostics capture most of this market.

HPLC (High Performance Liquid Chromatography) SYSTEMS

The demand for HPLC systems and accessories is accelerating as developments such as microprocessor automation has made analytical and preparative HPLC much easier to perform. In 1987, the Theta Corp. estimated HPLC system sales at \$277 million, with an overall market growth rate of about 15%. Theta expects this rate of growth to continue through 1991, by which time the market should be worth about \$440 million. Columns and the biotechnology segment should grow fastest, the latter rising 30% per year. Increased demand for HPLC instrumentation has prompted many firms to enter this competitive market.

HEMATOLOGY ANALYZERS

The total market for hematology analyzers of all types in the U.S. is estimated to be worth over \$300 million as of 1987. New advances in fluid counting technology have increased the capability of automated instruments to perform analysis of many more cell types. Analyzers are now available to automate platelet counting on whole blood simultaneously with the complete blood count. In addition, new technologies in laser imaging have enabled the differentiation of white cell subclasses, thus automating the classic differential count.

ION SELECTIVE ANALYZERS

Specific ion electrodes are used for determining clinically important analytes such as ionized calcium and various other clinical chemistry tests. Many of these are utilized in small labs and doctor's offices. The Department of Commerce reports, in its annual Current Industrial Report about "Instruments & Related Products", that U.S. manufacturers' shipments of ion selective electrodes and meters totalled \$18.5 million in 1986, down slightly from \$18.9 million the year before. Since 1976, sales of these instruments have risen five-fold.

LIQUID SCINTILLATION COUNTERS

This was a \$24 million market in 1986, and is projected to reach \$27 million by 1988.

PH METERS AND ELECTRODES

There are two types of apparatus used in pH determinations: laboratory pH and process pH. This was a \$27 million market in 1986, with an estimated growth rate of 95 annually. Sales by U.S. producers were as high as \$39 million during 1982, but have trended down slightly in recent years. The market should approach \$31 million by 1988.

SPECTROSCOPY

Theta Corp. estimates the market size for the four main instrument categories to reach about \$495 million by 1989. These four categories are:

- * mass spectrometers
- * Fourier transform infrared spectrometers
- * nuclear magnetic resonance spectrometers
- * X-ray spectrometers

The use of MRI (magnetic resonance imaging), FTIR (Fourier transform infrared spectroscopy), atomic absorption, and mass spectroscopy in the clinical area has generated new and different applications in this market.

The major suppliers to this market include: Applied Research Labs, Bruker Instrument, Digilab, Finnigan, Hewlett-Packard, IBM, JEOL, Kevex Corp., Nicolet Instruments, Phillips, Princeton-Gamma Tech, Siemens, Tracor Northern, and Varian Associates.

MAJOR TESTING TECHNIQUES

MICROBIOLOGY TESTING

This is a highly fragmented clinical market (hospitals, commercial labs, outpatient clinics, group practices, urgent care centers). It includes the following markets for instruments and equipment: automated and semi-automated ID/MIC systems, bacteriuria/emia confirmation instruments, collection and transport equipment, colony counters, immunodiagnostic instruments, and incubation/environmental equipment.

Continued.....

NON-ISOTOPIC IMMUNOASSAY

This clinical market involves the following testing methodologies:

- * enzyme immunoassay (EIA)
- * fluorescent immunoassay (FIA)
- * nephelometric immunoassay (NIA)
- * luminescent immunoassay

Rather than seeing a rapid demise of RIA, Theta Corp. believes the future is bright, with projected annual growth rates of 15-20%. RIAs will simply become a smaller share of a larger market.

TUMOR MARKERS

With a steadily rising cancer death rate, and an aging population, tumor markers are becoming an important market. The market was estimated at \$11 million in early 1987, and is expected to grow 25% yearly. The diversity of new diagnostic tests introduced will lead to development of a combination of markers and the popularization of tumor marker panels. Physicians feel more comfortable with tests that provide an overview, so they will order more tumor marker tests per patient.

The main tumor markers currently used in clinical labs are: CEA, CA-19-9, CA-125, LASA, HCG, Alpha-fetoprotein, and B-protein.

THE MEDICAL LABORATORIES INDUSTRY

THE LAB INSTRUMENTATION MARKET
(\$ Millions)

**Total U.S. Mfrs. Sales of Clinical Lab
Instrumentation**

(Includes Instruments
used in the clinical laboratory for
measuring, analyzing & processing
clinical specimens)

1979	\$198.4
1980	226.4
1981	439.7
1982	641.1
1983	744.3
1984	715.3
1985	631.9
1986	610.1

**SOURCE: U.S. Dept. of Commerce, Current Industrial Rep
Selected Instruments & Related Products**

THE MEDICAL LABORATORIES INDUSTRY

THE LAB INSTRUMENTATION MARKET

U.S. MANUFACTURERS' SALES OF CLINICAL LAB INSTRUMENTS, BY TYPE
(\$ Millions)

--- Chemistry Instruments ---(1) ---Hematology Instruments---(2)

	Unit Sales	Value	Unit Sales	Value
1979	*	*	7,686*	\$120.6*
1980	*	*	7,941*	139.7*
1981	12,804	\$134.2	9,998	134.5
1982	15,057	160.8	8,068	142.3
1983	10,934	223.6	11,667	184.2
1984	14,324	356.2	4,640	99.9
1985	10,547	334.0	5,962	106.7
1986	10,237	257.4	8,392	154.8

* Data combined with hematology instruments sales this year.

(1) Insts. to measure & identify substances, e.g. metabolites, enzymes, drugs.

(2) Insts. to measure & identify substances or cells contained in blood or substances influencing development & clotting of blood, e.g. cell counting coagulation factors.

---Microbiology instruments---(3) ---Histology Instruments---(4)

	Unit Sales	Value	Unit Sales	Value
1979	NA	\$ 31.8*	NA	*
1980	NA	34.9*	NA	*
1981	NA	39.6*	NA	*
1982	NA	64.1*	NA	*
1983	NA	72.0*	NA	*
1984	NA	87.0*	NA	*
1985	6,175	25.8	7,901	\$57.7
1986	5,903	24.4	9,148	77.3

NA _ Data not available

* Microbiology, histology, and blood bank/immunology insts. sales combined.

* Microbiology and histology insts. sales combined.

(3) Insts. to enumerate or identify pathenogenic organisms or measure their susceptibility to anti-microbial agents.

(4) Insts. to process tissue & cells, e.g. tissue processors, cell stainers.

THE MEDICAL LABORATORIES INDUSTRY

THE LAB INSTRUMENTATION MARKET

LAB ELECTROCHEMICAL INSTRUMENTS SALES BY U.S. MANUFACTURERS
BY TYPE (\$ Millions)

	<u>PH Electrodes And Meters</u>	<u>Ion Selective Electrodes And Meters</u>	<u>Electrophoresis Chambers & Supplies</u>
1976	\$16.1	\$3.6	\$27.9
1977	15.3	4.4	20.1
1978	24.5	6.6	37.3
1979	32.3	8.7	13.8
1980	36.3	10.9	17.2
1981	38.1	13.9	23.5
1982	39.2	15.2	26.9
1983	38.2	17.4	28.7
1984	37.1	21.9	21.0
1985	29.3	18.9	40.7
1986	27.0	18.5	35.5

	<u>Lab Type Coulometric Analyzers</u>
1983	\$23.3
1984	18.8
1985	21.1

Note: Unit sales not available for the above instruments, only dollar value of mfr. shipments.

THE MEDICAL LABORATORIES INDUSTRY

THE LAB INSTRUMENTATION MARKET

CHROMATOGRAPHIC INSTRUMENTS AND SAMPLE & FLOW COUNTING
INSTRUMENTS SALES BY U.S. MANUFACTURERS
(\$ Millions)

----- CHROMATOGRAPHIC INSTRUMENTS -----

	---- Gas ----		--- Liquid & Other (paper, gel, TLC) ---	
	Unit Sales	Value	Unit Sales	Value
1976	7,536	\$72.7	7,027	\$33.6
1977	24,353	91.2	11,503	53.2
1978	25,674	110.0	29,578	96.1
1979	28,615	123.5	22,961	98.6
1980	33,970	154.5	25,817	118.2
1981	21,868	134.4	30,634	129.3
1982	21,271	130.1	33,110	165.8
1983	26,512	124.1	35,735	214.4
1984	31,225	142.8	NA	243.4
1985	44,393	137.6	37,833	214.7
1986	52,563	149.5	39,891	241.1

---Sample & Flow Counting---
Systems (manual & automatic)

	Unit Sales	Value
1977	NA	\$24.6
1978	NA	26.7
1979	NA	37.4
1980	NA	40.6
1981	NA	33.5
1982	NA	28.7
1983	NA	29.5
1984	NA	34.7
1985	NA	36.0
1986	NA	33.1

NA - Data not available

THE MEDICAL LABORATORIES INDUSTRY

THE LAB INSTRUMENTATION MARKET

**U.S. MANUFACTURERS' SALES OF FLAME & OTHER PHOTOMETERS,
AND MISCELLANEOUS OTHER CLINICAL LAB INSTRUMENTS
(\$ Millions)**

	Photometers (Flame & other: fluorescent, light scattering reflectants, helium glow, light measuring)	Miscellaneous Other Clinical Lab Instruments	
	<u>Value</u>	<u>Unit Sales</u>	<u>Value</u>
1979	\$6.5	11,737	\$45.9
1980	6.9	12,197	51.8
1981	6.9	19,910	131.4
1982	5.0	18,873	274.0
1983	6.8	21,798	264.5
1984	10.8	16,840	172.2
1985	8.7	9,800	107.7
1986	NA	10,148	96.3

NA - Data not available

PROFILES OF SELECTED LABORATORY INSTRUMENT MANUFACTURERS

ABBOTT LABORATORIES

Abbott Labs is a major diversified health care firm, with strong positions in the areas of nutritional therapy, hospital and laboratory supplies, pharmaceuticals and diagnostic products, including AIDS testing. 1986 sales totalled \$3.808 billion, up from \$3.36 billion the prior year.

The company is an important manufacturer of health care-oriented products, with 1986 industry segment breakdowns as follows:

	<u>SALES</u>	<u>PROFITS</u>
Pharmaceutical & nutritional products	54 %	72 %
Hospital & laboratory	46	28

Hospital and laboratory products include intravenous and irrigating fluids and related equipment (15% of sales), venipuncture products, anesthetics, critical care and suctioning equipment, diagnostic instruments and tests, and other specialty products for hospitals and clinical labs.

Abbott, the world leader in AIDS diagnostics, was first to receive FDA approval for the current AIDS antibody tests. The antigen tests are expected to provide earlier detection of AIDS than do the antibody tests. Also, during the second quarter of 1987 Abbott introduced two new diagnostic products: the IMx system, which eliminates most of the manual steps necessary to perform immunoassays, and the ADx system, which allows for greater flexibility in abused drug testing.

Sales for 1988 are expected (by Standard & Poors) to show further improvement, aided by gains in established pharmaceutical, nutritional and hospital & lab products lines, as well as contributions from new products. Profitability should benefit from the better volume, productivity gains, and a lower tax rate. Sales for the nine months ended Spt. 30, 1987 increased 15%, year to year. Earnings for 1988 are projected at about \$3.20 a share, up from the \$2.80 indicated for 1987. International operations accounted for about 31% of sales and 22% of profits in 1986.

BECTON DICKINSON & CO.

Becton Dickinson manufactures a broad line of medical, surgical, laboratory and diagnostic products, including needles, syringes, intravenous catheters, blood collecting equipment, monoclonal antibodies, diabetes care kits, and bacteriological culture media. The company also makes protective clothing for industry, and owns 20% of Applied Biosystems. Deseret Medical was acquired in 1986. International business represents 34% of total sales, and the firm employs 19,900.

Becton Dickinson's 1987 sales totalled \$1.582 billion, and are estimated by Value Line to rise to \$1.8 billion. Sales of medical products are expected to benefit from moderately higher domestic demand.

B-D is presently focusing on the Far East, and will complete construction of a new Singapore plant this year. A weak dollar and fear over the spread of AIDS should help foreign marketing efforts. In the diagnostics segment, new products based on monoclonal antibody technology should contribute to sales growth. The company is introducing its *Afinity* line of tests for hospital lab use and a similar series for the physician office market. Older offerings, which permit hospitals to identify bacteria in blood samples and allow physicians to quickly analyze blood components, will probably continue to perform well. Sales of cell sorters should rise following an expansion of the customer service force last year.

Becton might leverage its diagnostics research through the development of new therapeutic agents. Five areas have been identified in which the firm's technological expertise could pay off. These are: prevention of organ transplant rejection, treatment of autoimmune disorders, development of an anti-AIDS therapy, stimulation of the immune system's killer cells to combat cancer, and an improvement in bone marrow transplantation. Value Line believes that the firm is seeking partners to assist in the research, and to ultimately market the products through licensing or joint venture agreements.

BIO-RAD LABORATORIES

This company is a leader in the fields of clinical diagnostics, separations chemistry and analytical instrumentation. Bio-Rad manufactures a broad range of high-tech products used mainly for the separation, analysis and measurement of complex chemical mixtures. Sales and operating profits in 1986 were broken down as follows:

See next page.....

	<u>SALES</u>	<u>PROFITS</u>
Research products	41 %	38 %
Diagnostic products	31	50
Analytical Instruments	28	12

International operations accounted for 44% of sales and 30% of operating income. Total revenues in 1986 amounted to \$127 million, up from \$102 million in 1985,

Products of the Diagnostics group include clinical diagnostic test kits and reagents, control sera and a fluorescent immunoassay instrument system for the clinical diagnostics laboratory, which eliminates the need for radioactive tracers.

The Analytical Instrumentation group develops and sells sophisticated instruments for analysis and process control, including Fourier transform infrared spectrometers, film thickness gauges, and tonometers. It also publishes spectral reference data.

In September of 1986 Bio-Rad applied to the FDA for an improved AIDS test that appears to be able to predict whether a person exposed to the AIDS virus will actually develop the disease.

KEYEX CORP.

Kevex Corp. designs, manufactures and services analytical spectrometer systems and related products, and provides laboratory analysis services. The division of revenues in recent fiscal years was as follows:

	<u>1986</u>	<u>1985</u>
Systems and parts sales	80 %	77 %
Service revenues	20	23

The company's spectrometers are used to determine the chemical elements and their concentrations in many types of organic and inorganic materials, without altering or destroying the sample under examination. Kevex's analytical instrument product line consists of microanalysis and bulk

analysis X-ray energy spectrometer systems, dedicated industrial X-ray fluorescence spectrometer systems and electron spectroscopy for chemical analysis systems.

Laboratory analysis services are provided through the Surface Science Laboratories unit (acquired in Jan. 1985). Domestic sales are made primarily to end-users through a direct sales staff and a network of independent reps.

KeveX had 1986 sales of \$29.2 million, and the firm was hurt by a \$1.6 million charge related to obsolete inventory and a restructuring of foreign operations, as well as by higher operating costs. Net revenues for the nine months to April 30, 1987, advanced 20%, year to year, reflecting increased sales of energy dispersive X-ray spectroscopy and ESCA spectrometers, as well as higher service revenues.

NICOLET INSTRUMENT CORP.

Nicolet Instrument manufactures testing instruments used in chemical analysis, medical research and diagnosis, industrial quality control, manufacturing, engineering, and other types of product testing. The company serves these markets: analytical (48% of 1986 sales), test and measurement (24%), and biomedical (28%). Foreign sales accounted for 42% of total sales, and the firm employs 1,128 workers.

1987 revenues amounted to about \$135 million, and Value Line estimates \$130 million for 1988. The company took a \$5.7 million loss in the December quarter, and a new company Chairman took office on March 3rd. It appears unlikely that the December quarter actions did enough to change operating losses into profits. Additional moves by Nicolet would seem probable, but may remain undefined until the new chairman makes his assessments.

Nicolet has developed what is probably the most advanced of hearing aids. Initial shipments of the two-piece design are imminent, and a one-piece unit is to follow within a year. Nicolet can probably revitalize its instrument business enough by 1990-92 to match its previous earnings record of a dollar a share.

PERKIN-ELMER

Perkin-Elmer's business segments include: analytical instrumentation, semiconductor processing equipment, optical systems, surface technology systems, avionics, and computers. Analytical instrument sales (Instruments Group) rose 15% to \$416 million in 1987, following an 11% gain the year before, and orders were higher (\$413 million). There was some strengthening of U.S. markets (environmental & pharmaceutical sectors), but the main contributor to improved results was the strength of European and Far East markets. Improved market conditions, as well as a beefed up sales force and favorable currency translations all contributed. Perkin-Elmer has a long-established presence in the United Kingdom and West Germany as well.

The company introduced many new products last year, including: a quality control package for its laboratory information management system, an advanced high sensitivity array detector for liquid chromatography, new environmental detectors for gas chromatography, faster and more sensitive Fourier transform infrared spectrophotometers, a reduced-cost inductively coupled plasma emission spectrometer, and a faster elemental analyzer.

Perkin-Elmer has introduced advanced products for analytical chemistry in the techniques of atomic and infrared spectroscopy, and in liquid chromatography. Its new Model 1600 infrared spectrometer promises to be the industry's first truly affordable high performance Fourier transform infrared instrument. The firm's analytical instrument business is now at record levels and is continuing to improve.

Following is a 5-year financial analysis of Perkin-Elmer's **Instrument Group**.....

	<u>1983</u>	<u>1984</u>	<u>1985</u>	<u>1986</u>	<u>1987</u>
	(\$ Millions) (Years Ended July 31)				
Net Sales	\$278.9	\$306.8	\$327.2	\$362.6	\$416.1
Operating Profit	28.3	25.2	33.3	34.6	43.5
Net Orders	277.5	315.2	340.0	372.1	413.2

VARIAN ASSOCIATES

Varian Associates produces a broad line of electron tubes, analytical instruments, semiconductor production equipment, and medical equipment. A return to profitability is forecast for fiscal 1987 (by Standard & Poors), based on somewhat stronger demand, better cost control, and the absence of nonrecurring charges. 1986 revenues were \$891 million, and sales for the first quarter ended Jan. 2, 1986 rose 1.0%, year to year.

Varian serves communications, defense, industrial production, and health care markets. Contributions to sales and profits, for 1986, were as follows:

	<u>SALES</u>	<u>PROFITS (\$ Mill.)</u>
Electron devices	47 %	\$ 20
Analytical instruments	19	2
Semiconductor equipment	15	-28
Medical & industrial instruments	19	11

Foreign business accounted for 23% of sales and a \$22 million pretax profit in fiscal 1986.

The instrument group supplies analytical instruments for the determination of chemical structure, composition, or both. The instruments are used in industrial, academic, and governmental labs throughout the world.

MAJOR U.S. MANUFACTURERS OF LABORATORY INSTRUMENTATION

Key:

- 1 - Medical Instruments
- 2 - Laboratory Apparatus/Supplies
- 3 - Analytical Instruments

=====

Alcon Laboratories Inc. [1]
6201 S. Freeway, Ft. Worth, TX 76134

American Caduceus Industries [1]
Div. of Schuco, 201 Hillside Avenue, Box 246, Williston Park, NY 11596

American Dade [2]
Div. of American Hospital Supply Corp., Box 520672, Miami, FL 33152

American Hospital Supply Corp. [2]
Scientific Products Div., 1430 Waukegan Road, McGaw Park, IL 60085

American Instrument Co. [1]
Div. of Travenol Laboratories Inc., Washington Blvd., Savage, MD 20863

American Optical Corp. [1]
14 Mechanic Street, Southbridge, MA 01550

American Optical Corp. [2]
Scientific Instrument Div., Box 123, Buffalo, NY 14240

American V. Mueller [1]
Div. of American Hospital Supply Corp., 6600 W. Touhy Ave., Chicago, IL 60648

Analytab Products [2]
Div. of Sherwood Medical Labs, 200 Express Street, Plainview, NY 11803

Anderson (H. W.) Products Inc. [1]
221 South Street, Oyster Bay, NY 11771

Angel Engineering Corp. [1]
Div. of Frogotronic Inc., 30 Lindeman Drive, Trumbull, CT 06611

Astra Tool & Instrument Mfg. Corp [1]
8473 Parsons Blvd., Jamaica, NY 11432

BBL [1]
250 Schilling Drive Box 243, Cockeysville, MD 21030

Bard (C. R.) Inc. [1]
Urological Div. Rte. 12, Fitzwilliam, NH 03447

Becton Dickinson & Co. [1]
383 Hillen Road, Baltimore, MD 21204

Becton Dickinson & Company, Corp. [1/2]
Mack Centre Drive, Paramus, NJ 07652

Becton Dickinson Immuno Diagnostic [2]
Div. of Becton, Dickinson & Co., Mountain View Avenue, Orangeburg, NY 10962

Bio-Rad Laboratories Inc. [3]
Digilab Div., 237 Putnam Avenue, Cambridge, MA 02139

Bio/Data Corp. [1]
Box 250, Hatboro, PA 19040

Biotronics [1]
Div. of Cavitron Corp., 1902 McGraw Avenue, Irvine, CA 92714

Bobbitt Laboratories Inc. [2]
1834 W. Davis Street, Burlington, NC 27215

Boehm Surgical Instrument Corp. [1]
966 Chili Avenue, Rochester, NY 14611

Brice Manufacturing Co. [1]
11395 Bradley Avenue, Pacoima, CA 91331

Brinkmann Instruments Co. [2]
Cantiaque Road, Westbury, NY 11590

Bristoline Inc. [1]
248 Buffalo Avenue, Freeport, NY 11520

Buchler Instruments [2]
1327 16th Street, Ft. Lee, NJ 07024

Burrell Corp. [2]
2223 Fifth Avenue, Pittsburgh, PA 15219

Burron Medical Inc. [1]
B. Braun of America Co., 824 12th Avenue, Bethlehem, PA 18018

Burton Div. [1]
Cavitron Corp., 7922 Haskell Avenue, Van Nuys, CA 91406

Carbomedics Inc. [1]
Box 14566, Austin, TX 78761

Celltrak Diagnostic Systems Inc. [1]
30 Lindeman Drive, Trumbull, CT 06611

Clay Adams [1]
Div. of Becton, Dickinson & Co., 290 Wabro Road, Parsippany, NJ 07054

Clinical Data Inc. [1]
1172 Commonwealth Avenue, Allston, MA 02134

Codman & Shurtleff [1]
Industrial Park, New Bedford, MA 02745

Collins Inc. (Warren E.) [1]
220 Wood Road, Braintree, MA 02184

Columbus Dental Manufacturing Co. (The) [1]
Box 620, St. Louis, MO 63188

Columbia Research Corp. [1]
1 Metropolitan Grove Road, Gaithersburg, MD 20760

Consolidated Instruments Corp. [1]
8800 Kelso Drive, Baltimore, MD 21221

Consolidated Machine Corp. [1]
76 Ashford Street, Boston, MA 02134

Consolidated Medical Equipment Inc. [1]
310 Broad Street, Utica, NY 13501

Cooper Bio Medical Inc. [2]
Halls Mill Road, Box 650, Freehold, NJ 07728

Corning Glass Works [2]
Houghton Park, Corning, NY 14830

Crescent Manufacturing Co. [2]
7750 W. 47th Street, Lyons, IL 60534

Curtin Matheson Scientific Inc. [2]
1850 Greenleaf Avenue, Elk Grove Village, IL 60007

Damon Instructional Systems Div. [2]
80 Wilson Way, Westwood, MA 02090

Dantec Electronics Inc. [1]
6 Pearl Court, Allendale, NJ 07401

Datascope Corp. [1]
580 Winters Avenue, Box 5, Paramus, NJ 07652

Davis & Geck [1]
Div. of American Cyanamid Co., Casper Street, Danbury, CT 06810

Daxor Corp. [1]
645 Madison Avenue, New York, NY 10022

Dayton Flexible Products [1]
Div. of Baxter Travenol Labs., 2210 Arbor Blvd., 2nd Fl., Dayton, OH 45439

Diagnostic Technology Inc. [1]
240 Motor Parkway, Hauppauge, NY 11788

Difco Laboratories Inc. [2]
920 Henry Street, Box 1058-A, Detroit, MI 48232

DuPont/Sorvall [2]
E. I. Du Pont DeNemours & Co., Inc., 1007 Market Street, Wilmington, DE 19898

Dynatech Corp. [1]
3 New England Executive Park, Burlington, MA 01803

Edmund Scientific Corp. [2]
101 E. Gloucester Pike, Barrington, NJ 08007

Electro Audio Dynamics Inc. [1]
98 Cutter Mill Road, Great Neck, NY 11021

Electro-Biology Inc. [1]
300 Fairfield Road, Fairfield, NJ 07006

Electro-Catheter Corp. [1]
2100 Felver Court, Box 1214 C, Rahway, NJ 07065

Elscint Inc. [1]
930 Commonwealth Ave., Box 679, Boston, MA 02215

Engineering Dynamics Corp. [1]
120 Stedman Street, Lowell, MA 01851

Fiberoptics Engineering Corp. [1]
134 Water Street, Box 268, Wakefield, MA 01880

Fisher Scientific Co. [2]
1410 Wayne Avenue, Indiana, PA 15701

Flexodent Corp. [1]
4232 E. Catus Road, Ste. 107, Phoenix, AZ 85032

Fotodyne Inc. [2]
16700 W. Victor Road, New Berlin, WI 53151

Foxboro Co. (The) [2]
80 Republic Drive, North Haven, CT 06473

Frigitronics of Conn. Inc. [1]
770 River Road, Shelton, CT 06484

Gelman Instrument Co. [2]
600 S. Wagner Road, Ann Arbor, MI 48106

General Scientific Equipment Co. [1]
Linekiln Pike & Williams Avenue, Philadelphia, PA 19150

Gould Inc. [1]
Cardio-Pulmonary Products Div., 2855 Mangum, Houston, TX 77092

Gulf & Western Manufacturing Co. [1]
Applied Science Laboratories Div., 335 Bear Hill Road, Waltham, MA 02154

Hays Medical Inc. [1]
500 Bostwick Avenue, Bridgeport, CT 06605

Helmack Products Corp. [1]
528 Kelso Street, Box 73, Flint, MI 48501

Hemotec Inc. [1]
13 Inverness Way, Englewood, CO 80112

Hewlett-Packard Co. [2]
1820 Embarcadero Road, Palo Alto, CA 94303

Hobbs Medical Inc. [1]
10 Spring Street, Stafford Springs, CT 06076

Holgrath Corp. (The) [1]
Sub. of Virginia Industries, 30 Knotter Drive, Cheshire, CT 06410

Hygeia Medical Supply Corp. [1]
582 Westbury Avenue, Carle Place, NY 11514

International Medical Corp. [1]
64 Inverness Drive, Englewood, CA 80112

Jefferson Electric [1]
Div. of Magnetek Inc., 1400 Center Circle Drive, Downer's Grove, IL 60515

Kimble Terumo Inc. [1]
Blue Ball Road, Box 605, Elkton, MD 21921

Kratos Analytical Instruments [2]
170 Williams Drive, Ramsey, NJ 07446

La Pine Scientific Co. [2]
6001 S. Knox Avenue, Chicago, IL 60629

Lab-Line Instruments Inc. [2]
15th & Bloomingdale Avenues, Melrose Park, IL 60160

Labarge Inc. [1]
Electronic Div., 9422 E. 55th Place, Tulsa, OK 74145

Laboratory Assocs. Inc. [1]
11 Coker, Belmont, MA 02179

Lafayette Instrument Co. [1]
Sagamore Pkwy., Box 5729, Lafayette, IN 47903

Leeds & Northrup/Nester [2]
Instruments Div., 101 Buck Street, Box 666, Milville, NJ 08332

Life-Tech Instruments Inc. [1]
Box 36221, Houston, TX 77036

Lifeline Products Inc. [1]
857 N. Main Street Ext., Wallingford, CT 06492

Lifemed Technologies Inc. [1]
1400 West Belt, N. Houston, TX 77043

Lionville Systems Inc. [1]
311 Commerce Drive, Exton, PA 19341

Mada Medical Products Inc. [1]
60 Commerce Road, Carlstadt, NJ 07072

Mallinckrodt [2]
Forma Scientific Div., Mill Creek, Box 649, Marietta, OH 45750

Marcas Paper Mills Inc. [1]
5401 S. Western Blvd., Chicago, IL 60609

Meda Sonics Inc. [1]
Sub. of Colgate-Palmolive Co., 340 Pioneer Way, Box 726, Mtn. View, CA 94039

Medi-Dyne Instruments Inc. [1]
1 Warren-Washington Industrial Park, Glens Falls, NY 12801

Medi-Tech Co. [1]
480 Pleasant Street, Watertown, MA 02172

Medical Plastics Inc. [1]
650 Hollister Avenue, Bridgeport, CT 06607

Medisco-Federal Inc. [1]
Garnerville Industrial Terminal, Garnerville, NY 10923

Mennen Medical Inc. [1]
10123 Main Street, Clarence, NY 14031

Micrometrics Instrument Corp [2]
5681 Goshen Springs Road, Norcross, GA 30093

Miles Laboratories Inc. [2]
Miles Scientific Div., 30 W. 475 N. Aurora Road, Naperville, IL 60540

National Spectrographic Laboratories [2]
7650 Hub Pkwy., Cleveland, OH 44125

Neuro Systems Inc. [1]
2705 National Drive, Garland, TX 75041

Nicolet Instrument Corp. [2]
5225 Verona Road, Madison, WI 53711

Nova Medical Specialties [1]
Jackson Road, R.D. #2, Vincentown, NJ 08088

Novocol Chemical Manufacturing Co., Inc. [1]
575 Underhill Blvd., Syosset, NY 11791

Nuclear Assocs. [1]
100 Voice Road, Carle Place, NY 11514

Orion Scientific Instrument Corp. [2]
200 Saw Mill Rural Road, Box 268, Hawthorne, NY 10532

Orthopedic Equipment Co., Inc. [1]
Quad & Ecker Avenue, Bourbon, IN 46504

Owens-Illinois Inc. [2]
Kimble Div., Crystal Avenue, Box 230, Vineland, NJ 08360

Perkin-Elmer [2]
Oak Brook Instruments Div., 2000 York Road, Oak Brook, IL 60521

Perma-Type Rubber Co., Inc. [1]
Box 448, Farmington, CT 06032

Peter, Strong & Co., Inc. [1]
Box 807, Southbury, CT 06488

Physio-Control Corp. [1]
11811 Willows Road, Redmond, WA 98052

Prateus Inc. [1]
1003 S. Main Street, Bellingham, MA 02019

Pymah Corp. [1]
Box 1114, Somerville, NJ 08876

Ranging Inc. [2]
Box 308, E. Bloomfield, NY 14443

Renal Systems Inc. [1]
14905 28th Avenue N., Minneapolis, MN 55441

Rheem Manufacturing Co. [2]
Scientific Products Div., Aiken Road, Rt. 1, Box 275, Asheville, NC 28804

Richards Medical Co. [1]
1450 E. Brooks Road, Memphis, TN 38116

Rodale Electronics Corp. [1]
603 Chestnut Street, Garden City, NY 11530

Rudolph Inc. (Hans) [1]
7200 Wyandotte, Kansas City, MO 64114

Schroer Manufacturing Co. [1]
2221 Campbell, Kansas City, MO 64108

Scott Aviation [1]
Div. of Figgie International, 309 West Cronwell St., Box 569, Monroe, NC 28110

Shandon Southern Instruments Inc. [1/2]
515 Broad Street, Sewickley, PA 15143

Sherwood Medical [1]
Div. of American Home Products, Box 2568, Waterbury, CT 06720

Sherwood Medical Co. [1]
Box 147, Argyle, NY 12809

Skia Corp. [1]
5181 Lafayette Street, Santa Clara, CA 95050

Sonicor Instrument Corp. [1]
100 Wartburg Avenue, Copiague, NY 11726

South Mountain Medical Inc. [1]
537 Sweeten Creek Industrial Park, Asheville, NC 28804

Spacelabs Inc. [1]
20550 Prairie Street, Chatsworth, CA 91311

Spectra Physics Inc. [2]
Auto Lab. Div., 3333 N. First Street, San Jose, CA 95134

Spectrum X-Ray Corp. [1]
Ryan Avenue, Box 155, Westville, NJ 08093

Spex Industries Inc. [2]
3880 Park Avenue, Edison, NJ 08820

Stephenson Industries Inc. [1]
Box 1000, Farmingdale, NJ 07727

Survival Technology Inc. [1]
8101 Glenbrook Road, Bethesda, MD 20814

Sybron Corp. [1/2]
Medical Products Div., 1777 E. Henrietta Road, Box 23077, Rochester, NY 14692

Sybron Corp. [2]
Thermolyne Corp. Sub., 2555 Kerper Blvd., Dubuque, IA 52001

Synergetics Inc. [1]
1219 S. Main Street, Gainesville, FL 32601

TNCO Inc. [1]
Box 223, Whitman, MA 02382

Techne Inc. [1]
3700 Brunswick Pike, Princeton, NJ 08540

Technicon Instruments Corp. [2]
Benedict Avenue, Tarrytown, NY 10591

Techscience Industries Inc. [1]
85 Portland Avenue, Bergenfield, NJ 07621

Telstar Instruments Corp. [1]
Box 1487, Southold, NY 11971

Thomas Scientific [2]
Vine Street at Third, Box 779, Philadelphia, PA 19105

Thomas Tool Co. [1]
1019 E. Michigan Avenue, Battle Creek, MI 49017

Toolmatic Corp. of Connecticut [1]
300 Shaw Road, N. Branford, CT 06471

Torboot Co., Inc. [1]
1185 Jefferson Blvd., Warwick, RI 02886

Tracor Inc. [3]
Instruments Div., 6500 Tracor Lane, Bldg. 27, Austin, TX 78721

Tri-WG Inc. [1]
Box 905, Valley City, ND 58072

United Metal Fabricators Inc. [1]
409 Eisenhower, Johnstown, PA 15904

Varian Assocs. Instrument Group [3]
611 Hansen Way, Palo Alto, CA 94303

Vernitron Medical Products [2]
5 Empire Blvd., Carlstadt, NJ 07072

Vista Laboratories Inc. [1]
718 N. Fourth Street, Phoenix, AZ 85001

Vita Needle Co. [1]
919 Great Plain Avenue, Needham, MA 02192

Wampole Laboratories [2]
Div. of Carter-Wallace Inc., Half Acre Road, Box 1, Cranbury, NJ 08512

Waters Assocs. Inc. [2/3]
34 Maple Street, Milford, MA 01757

Weck & Co., Inc. (Edward) [1]
Division of Squibb Corp., Box 12600, Research Triangle Park, NC 27709

Williams Instruments Inc. [1]
2721 White Settlement Road, Ft. Worth, TX 76107

Wocher & Son Co. (Max) [1]
11359 Grooms Road, Cincinnati, OH 45242

Zeus Industrial Products Inc. [2]
Foot of Thompson Street, Raritan, NJ 08869

Count: 162

Source: MacRae's Blue Book, OEM Directory

**SELECTED CLINICAL LAB INDUSTRY PROFESSIONAL & TRADE
ASSOCIATIONS AND ORGANIZATIONS.**

American Association of Blood Banks

30 North Michigan Ave.
Chicago, IL 60602

American Council of Independent Laboratories

1725 K St. N.W.
Washington, DC 20006 (202-887-5872)

The American Institute of Biological Sciences

1401 Wilson Blvd.
Arlington, VA 22209

Board of Registry

American Society of Clinical Pathologists

P.O. Box 4872
Chicago, IL 60680

American Society of Cytology

Health Sciences Center, Suite 1006
Thomas Jefferson University
130 South 9th Street
Philadelphia, PA 19107

Analytical Laboratory Managers Association

P.O. Box 258
Montchanin, DE 19710 (302-571-8216)

Clinical Laboratory Management Association

193-195 W. Lancaster Ave.
Paoli, PA 19301 (215-647-8970)

Health Care Financing Administration

Office of Research & Demonstrations
2-F-2 Oak Meadows Bldg.
6325 Security Blvd.
Baltimore, MD 21207 (301-966-6683)

Health Industry Distributors Association

1701 Pennsylvania Ave. N.W.
Suite 470
Washington, DC 20006 (202-659-0050)

Health Industry Manufacturers Association

1030 15th St. N.W.

Suite 1100

Washington, DC 20005 (202-452-8240)

International Society For Clinical Laboratory Technology

818 Olive, Suite 918

St. Louis, MO 63101 (314-241-1445)

National Association of Laboratory Suppliers

P.O. Box 1229

Metairie, LA 70004

National Council on Health Laboratory Services

1735 Yale Place

Rockville, MD 20850 (301-594-9712)

TRADE JOURNALS, NEWSLETTERS & PERIODICALS

Medical Lab Observer

Medical Economics Co.

Oradell, NJ 07649 (201-262-3030)

McKnight Medical Communications

550 Frontage Rd.

Northfield, IL 60093 (312-446-1622)

(publisher of: Hospital Purchasing News & Medical Products Sales)

"The National Intelligence Report" (newsletter)

Washington G-2 Reports (legislative affairs, proficiency testing, etc.)

1111 14th St. N.W., Suite 1010

Washington, DC 20005 (202-789-1034) (Dennis Weissman, editor)

also: **"The Medical Office Report"** (newsletter-directed to pathologists,
cardiologists)

CONSULTING FIRMS

David Birenbaum & Associates

818 Olive, Suite 918

St. Louis, MO 63101 (314-241-1445)

* Manages the **American Assoc. of Bioanalysts**